

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP F.01.c**

**PURPOSE:** To hold a kickoff meeting with the Office of Enforcement and Compliance Assurance (OECA).

**SCOPE:** Held kickoff meeting with OECA to discuss objective and scope of the assignment as they relate to the Congressional requests.

**SOURCE:** A) Meeting agenda sent ahead of kickoff meeting.  
B) See the list of meeting participants below.

**DATE and TIME:** 3/21/19, 3:00 – 3:30 PM EDT.

**LOCATION:** Teleconference.

**PARTICIPANTS:**

**OECA**

Shaun Burke, Senior Environmental Engineer, Office of Civil Enforcement, Air Enforcement Division, Stationary Source Enforcement Branch, (202) 564-1039

Sara Ayres, Civil Engineer, Office of Compliance, Monitoring, Assistance, and Media Programs Division, Air Branch, (312) 353-6266

**OIG – Office of Audit and Evaluation – Air Directorate**

Jim Hatfield, Director, (919) 541-1030

Renee McGhee-Lenart, Project Manager, (913) 551-7534

Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one meeting.

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	3/22/19
<b>Approved by:</b>	<b>Date</b>

**SUMMARY:** During the kickoff meeting, we

- Discussed the preliminary research evaluation objective, questions from the Congressional requesters, scope and methodology to answer the Congressional questions, and evaluation process.
- Discussed whether OECA has prioritized inspections at ethylene oxide-emitting facilities and systems to track such facilities.
- Established contact for ethylene oxide-emitting facilities.
- Next steps.

Noteworthy points from the kickoff meeting included:

(S)

**DETAILS:**

Renee sent the kickoff meeting agenda (Source A) ahead of the meeting. Below are the topics discussed (black text). Blue text are the responses and discussions that occurred during the meeting.

**KICKOFF MEETING AGENDA**  
**OIG Evaluation of EPA Actions to Address Air Toxics Emissions through Its Residual Risk and Technology Review Program**  
**March 21, 2019**

**I. Preliminary Research Evaluation Objective:**

Determine whether the EPA's residual risk and technology review (RTR) process has sufficiently identified and addressed any elevated cancer risks from air toxics emitted by facilities.

We also received 4 Congressional Requests concerning facilities that emit ethylene oxide. We will expand the scope of this assignment to address the Congressional Requests.

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Link: **A** Renee stated that we would be addressing the following questions:

- (1) Whether EPA senior political appointees instructed EPA inspectors to avoid conducting inspections at EtO emitting facilities across EPA Regions 5 and 6.
- (2) Have inspections by the EPA been conducted on [ethylene oxide-emitting] facilities in Regions 5 and 6? If not, why?
- (3) Whether the EPA complied with all statutory, regulatory and policy requirements and protocols in disclosing public health information about ethylene oxide air emissions from the Sterigenics facility in DuPage County, Illinois, the Medline Industries, Inc. facility in Lake County, Illinois and the Vantage Specialty Chemicals, Inc. facility in Lake County, Illinois.

The third question applies to Region 5, but we will determine whether this is an issue in Region 6 as well.

Renee next asked whether there were any questions about the Congressional questions we will be addressing in the audit. Shaun asked whether OIG can provide the Congressional questions in writing. Jim responded that we are unable to do that because OIG's response to the Congressional requests are not publicly available. Jim pointed out that the 1/18/19 and 11/1/18 press releases on Senator Duckworth's website provide information on Senator Duckworth's request that OIG look into EPA's response to ethylene oxide issues in Illinois. These press releases should give OECA an idea of what OIG will be examining. Renee added there are InsideEPA articles on the matter as well.

## **II. OIG Planned Scope and Methodology for Congressional Requests:**

We will interview EPA Region 5 and 6 managers and staff as well as OAR and OECA managers and staff. We will also analyze full compliance evaluation and partial compliance evaluation information to determine whether facilities that emit ethylene oxide have received timely full compliance evaluations. We will also research the statutory, regulatory, and policy requirements EPA must follow in disclosing public health information about ethylene oxide.

## **III. OIG Evaluation Process**

Renee stated that we are currently in the preliminary research (PR) phase of the assignment. At the end of PR, there will be three options for us:

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- We have enough information to write a report.
- We need to proceed into fieldwork to continue our assignment.
- We do not have any issues and will issue a close-out memo.

If we have enough information to write a report, we will have meetings to discuss findings. We would issue a discussion document with our findings. The discussion document is a way for us to fact check what we have found. You will have 15 days to provide written comments and/or meet with us to discuss your comments on the discussion document. We then take into consideration your comments on the discussion document to develop a draft report. You will have 30 days to comment on the draft report. There will also be an exit conference to discuss your comments on the draft report. Then the final report is issued.

Renee then asked whether there were any questions on our evaluation process. Shaun and Sara did not have any questions.

#### IV. Initial Questions for Discussion at Kickoff Meeting:

1. Has OECA prioritized conducting full compliance evaluations at ethylene-oxide emitting facilities?

(b) (5)

2. Is OECA working on any special initiatives regarding ethylene oxide emitting facilities?

(b) (5)

3. What data systems does OECA use to track the status of the facilities that emit ethylene oxide?

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(b) (5)

4. Is the October 2016 Clean Air Act Stationary Source Compliance Monitoring Strategy the most recent version of the document?

(b) (5)

**V. Establish Agency Contact(s) for the Following Topic Areas:**

- Ethylene-oxide facility contacts

Shaun stated that he would be the contact person or his boss, Greg Fried.

**VI. Next Steps:**

- Establish how often, and by what means, the OIG team will communicate with OECA managers to provide updates on the evaluation.

Sara said email is fine, and she can send up the chain.

Shaun said email is fine and to include Lauren Kabler and Apple Chapman.

Reviewer Comment (and Date of Review)	Team Response (and Date of Response)	Resolution (and Date of Resolution)
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Prepared by:	Date
Bao Chuong	3/22/19
Approved by:	Date

		WP approved. RML 3/27/19

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	3/22/19
<b>Approved by:</b>	<b>Date</b>

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.02.a**

**PURPOSE:** To interview Agency for Toxic Substances and Disease Registry (ATSDR) about its assistance to Region 5 on Sterigenics.

**SCOPE:** Held meeting with ATSDR about its assistance to Region 5 on Sterigenics.

**SOURCE:** A) Email communications between (b) (6) and ARD staff regarding modeling data.

B) ATSDR email containing examples of letter health consultations for Region 5 Air and Radiation Division.

C) Fact sheet on ethylene oxide, issued through ATSDR's partnership with the Great Lakes Center for Children's Environmental Health at the University of Illinois-Chicago (received in a 4/1/19 email from (b) (6)).

D) ATSDR public statement on the Sterigenics Letter Health Consultation document, which was sent to the Willowbrook Mayor on August 27, 2018, and then posted on the ATSDR webpage with the consultation document (received in a 4/1/19 email from (b) (6)).

E) ATSDR fact sheet on the Aug. 21st Letter Health Consultation document, prepared for distribution at the November 29<sup>th</sup> public meeting (received in a 4/1/19 email from (b) (6)).

F) Email showing (b) (5)

G) ATSDR, Letter Health Consultation: Evaluation of Potential Health Impacts from Ethylene Oxide Emissions, Sterigenics International, Inc., Willowbrook, Illinois, August 21, 2018

([https://www.atsdr.cdc.gov/HAC/pha/sterigenic/Sterigenics\\_International\\_Inc-508.pdf](https://www.atsdr.cdc.gov/HAC/pha/sterigenic/Sterigenics_International_Inc-508.pdf), accessed 11/13/18)

Prepared by:	Date
Bao Chuong	4/8/19
Approved by:	Date

**DATE and TIME:** 4/1 /19, 9:00 – 10:30 AM CDT.

**LOCATION:** ATSDR Central Regional Office in Chicago (same building as EPA Region 5). ATSDR is part of the Department of Health and Human Services.

**PARTICIPANTS:**

(b) (6)

**OIG – Office of Audit and Evaluation – Air Directorate**  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy points from the meeting include:

- EPA did not dictate or delay when ATSDR would release the Letter Health Consultation document on ethylene oxide emissions from Sterigenics in Willowbrook, Illinois. ATSDR was going to release the Letter Health Consultation document whenever it was ready, which was August 21, 2018.
- The Letter Health Consultation on ethylene oxide emissions from Sterigenics in Willowbrook, Illinois was not written for the public. A public statement and fact sheet have been issued for the Letter Health Consultation.

- (b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	4/8/19
<b>Approved by:</b>	<b>Date</b>

## **DETAILS:**

We met with ATSDR because they had provided assistance to Region 5 that resulted in a letter health consultation to the Region regarding ethylene oxide emissions from the Sterigenics facility in Willowbrook, Illinois. Source G is the letter health consultation. Below are details of the meeting.

### **OAE Air Directorate Background**

After introductions, Renee provided a brief background on who we are. Renee stated that we are both within OIG's Office of Audit and Evaluation (OAE). Within OAE, we are in the Air Directorate where we conduct audits/evaluations of air programs. Examples of air issues that the Air Directorate has looked at include air toxics, air enforcement, and concentrated animal feeding operations (CAFOs).

### **Audit Objectives**

Renee explained that that we initially started an audit of EPA's air toxics residual risk and technology review (RTR) process with an objective to determine whether the EPA's residual RTR process has sufficiently identified and addressed any elevated cancer risks from air toxics emitted by facilities. We then received four Congressional requests that focused on ethylene oxide. Instead of just keeping our original objective, we have added three additional questions to answer in our review:

- (1) Whether EPA senior political appointees instructed EPA inspectors to avoid conducting inspections at EtO emitting facilities across EPA Regions 5 and 6.
- (2) Have inspections by the EPA been conducted on [ethylene oxide-emitting] facilities in Regions 5 and 6? If not, why?
- (3) Whether the EPA complied with all statutory, regulatory and policy requirements and protocols in disclosing public health information about ethylene oxide air emissions from the Sterigenics facility in DuPage County, Illinois, the Medline Industries, Inc. facility in Lake County, Illinois and the Vantage Specialty Chemicals, Inc. facility in Lake County, Illinois.

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## Report Writing

(b) (6) asked whether there will be a report after the audit is completed. Renee responded that currently we are not sure whether there will be a report that will be issued. Renee went on to explain that If there is going to be a report, a discussion document would be issued first. The discussion document is similar to a fact-checking document to make sure that we all agree on the facts.

(b) (6) asked whether OIG would quote them by name. Renee responded that we do not quote by name. Instead, we would say something like "according to an ATSDR manager" or according to an ATSDR staff meeting."

## Background on ATSDR

**A** [Link:](#) (b) (6) provided an overview of ATSDR. He explained that ATSDR is the link between the Centers for Disease Control and Prevention (CDC) and EPA. ATSDR's mandate is to conduct health assessments at Superfund sites. However, ATSDR's role is broader than that. ATSDR's regional office (Chicago) has conducted assessment cases (letter health consultations) for Region 5's Air and Radiation Division (ARD). [\[Evaluator Note: Examples of these letter health consultations for ARD can be found in Source B.\]](#) ATSDR would document its opinion through Letter Health Consultations, such as the letter to Ed Nam, Director of Region 5's ARD. These assessment letters are usually used by ARD to support ARD's decisions. ATSDR has also conducted work for communities at their request.

(b) (6) . (b) (6) . Their role is to coordinate with EPA programs in the region and work with state health departments. Of the 6 states in Region 5, ATSDR has cooperative agreements with four of them. Illinois is not one of the four states. All ATSDR regional products have to go through clearance with their HQ in Atlanta. Some products must go to HHS in DC for clearance. ATSDR has a separate Congressional appropriation.

## ARD Request for ATSDR Assistance on Sterigenics

(b) (6), (b) (5)

<b>Prepared by:</b>	<b>Date</b>
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<b>Approved by:</b>	<b>Date</b>

(b) (5). Around late February or early March 2018, ARD formally asked ATSDR for assistance with assessing health impacts from ethylene oxide emissions from Sterigenics.

#### ATSDR Conducting the Health Assessment on Ethylene Oxide Emissions from Sterigenics

(b) (6), (b) (5)  
asked ARD whether they would conduct ambient monitoring because ATSDR was not going to conduct an assessment with just modeling data. Monitoring data are needed to corroborate the modeling data. ARD told her that they would conduct monitoring. (b) (6) confirmed that EPA conducted ambient monitoring in May 2018. EPA received the validated monitoring data around the second week of June 2018. ARD provided ATSDR with a copy of the validated monitoring data.

It took around four or five weeks for ATSDR to review the modeling and monitoring data and document the assessment. Once the report (i.e., letter health consultation) was drafted, it went to CDC in Atlanta for review, then it was released to Region 5. The draft report was issued to Ed Nam of ARD on 7/26/18. There was one iteration before 7/26/18. Between 7/26/18 and the final version dated 8/21/18, edits to the reference list were made, (b) (5)

Region 5 created a website on Sterigenics. On this website was a link to the final ATSDR report on the health assessment of ethylene oxide emissions from Sterigenics. The website went live for an hour, and then EPA HQ pulled the website down, but the link to the ATSDR report was still on the website.

The mayor of Willowbrook saw the website before it was pulled down. The mayor set up a public meeting soon after and asked ATSDR to be at the meeting. ATSDR agreed to be at the meeting to answer questions from the public.

There were challenges to communication with the public because the ATSDR report was not written for the general public. Source C is the fact sheet on ethylene oxide that ATSDR had worked on with University of Illinois – Chicago. Source D is the ATSDR public statement on the Sterigenics Letter Health Consultation document, which was sent to the Willowbrook Mayor on August 27, 2018, and then posted on the ATSDR

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webpage with the consultation document. Source E is the ATSDR fact sheet on the Aug. 21st Letter Health Consultation document, prepared for distribution at the November 29<sup>th</sup> public meeting. (b) (6) sent Sources C, D, and E to OIG after the meeting.

#### ATSDR Did Not Delay Release of the Letter Health Consultation on Sterigenics

(b) (6) stated that ATSDR did not delay the release of the letter health consultation on Sterigenics. They were going to release it whenever it was ready, which happened to be 8/21/18. EPA Office of Air Quality Planning and Standards (OAQPS) spoke to ATSDR, wanting to coordinate the release of ATSDR and NATA. In the end, ATSDR processed and released the letter health consultation on its schedule. ATSDR's release date was not dictated by OAQPS. If anything, the release of the letter health consultation on Sterigenics moved up the release date of the 2014 NATA.

#### ATSDR Involvement with Community

(b) (6) stated that the public and other agencies (besides EPA) can petition ATSDR to conduct a health assessment or help address concerns with toxic chemicals or substances, which ATSDR has done in the past for other communities. With respect to ethylene oxide, ATSDR has

- Worked with county health agencies.
- Participated on a meeting panel in November.
- Participated in a webinar for physicians last week.

(b) (6), (b) (5)

(b) (5)

(b) (5)

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Bao Chuong	4/8/19
Approved by:	Date



- (b) (5)

#### Background on Ethylene Oxide

(b) (6) noted that ethylene oxide is not a naturally occurring chemical. (b) (5)

#### Medline and Vantage in Lake County

(b) (6) noted that Vantage is a chemical plant and Medline is a sterilizer. (b) (5)

#### How Long Should Long-Term Ambient Monitoring Be Conducted

(b) (6) explained that it needs to be long enough to capture meteorological variability. The length of time also depends on the nature of emissions. You need to have enough data to say its representative of the area. You also need to conduct a spatial assessment of wind vectors.

#### Research on Improving Detection Limit for Ethylene Oxide

(b) (6), (b) (5)

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Approved by:	Date

(b) (6), (b) (5)

(b) (6), (b) (5)

(b) (6), (b) (5)

Reviewer Comment (and Date of Review)	Team Response (and Date of Response)	Resolution (and Date of Resolution)
		WP approved. RML 4/30/19

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	4/8/19
<b>Approved by:</b>	<b>Date</b>

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.02.aa**

**PURPOSE:** To interview (b) (6) regarding EPA's role in addressing ethylene oxide emissions.

**SCOPE:** Interviewed (b) (6) regarding EPA's role in addressing ethylene oxide emissions.

**SOURCE:** A) List of regional contacts for ethylene oxide coordination calls. (b) (6) provided to us after meeting.)

B) List of meetings with public affairs directors in the month leading up to the release of the 2014 NATA to the public. (b) (6) provided to us after meeting.)

C) See the list of meeting participants below.

**DATE and TIME:** 5/9/19, 4:30 – 6:00 PM EDT.

**LOCATION:** (b) (6)

**PARTICIPANTS:**

[Link:](#) WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach (b) (6)  
(b) (6), (b) (6)

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Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy points from the interview included:

- According to (b) (6), there are no written expectations and milestones associated with the two-prong strategy to address ethylene oxide emissions.
- The biweekly ethylene oxide coordination calls consist of a technical person and a communications person from each region. However, these calls have expanded to other people who submit notes and want to join in. The purpose of these calls is to find out where the regions are at with addressing ethylene oxide emissions and what their needs are.
- (b) (5), (b) (6)
- (b) (5), (b) (6)
- (b) (5), (b) (6)

**DETAILS:**

After introductions, the following questions were asked. (b) (6)'s responses are in blue text.

Background on (b) (6)

1. What is your title or role in (b) (6)

(b) (6)

2. How long have you been in your current position?

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Renee McGhee-Lenart	6/14/19
No comments.	

(b) (6)

3. Who do you report to?

(b) (6)

4. What are your responsibilities with respect to NATA and ethylene oxide?

(b) (6)

(b) (6) "Ethylene Oxide Coordination Calls"

5. (b) (6)

a. What is the purpose of these coordination calls?

(b) (5)

b. What type of issues are discussed?

(b) (5)

The calls tend to be technical. Every other week held.

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Bao Chuong	6/13/19
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Renee McGhee-Lenart	6/14/19
No comments.	

c. How often are the calls held?

Every other week.

d. Who is required to participate on these coordination calls?

Each region nominated a technical person and a communications person. The calls have expanded to other technical staff – anyone who sends notes and wants to join in. In some regions, the technical person is the Air and Radiation Division Director.

e. Could we get a list of the technical people and communications people from each region on the ethylene oxide coordination calls? Yes, I can provide that to you. [Evaluator note: After the meeting, (b) (6) provided us with the list. See Source A. As shown in Source A, the list covers people from Regions 2 through 8 since these regions contained the highest risk facilities as identified in the 2014 NATA.]

f. We heard that OAQPS had distributed a list of 25 ethylene oxide-emitting facilities that contribute to elevated cancer risks to the regions for them to focus on.

i. What are the expectations of regions with respect to these listed facilities?

[Link: WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docx](#)We were given the two-pronged strategy. One prong is addressing ethylene oxide emissions through rulemaking. The other prong is to identify emissions reductions that may be available. The regions are to focus on voluntary emissions reductions.

Expectations are not written.

ii. What are the milestones associated with these expectations?

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Renee McGhee-Lenart	6/14/19
No comments.	

[Link: WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docx](#)I'm not aware of any milestones. Regions have to work with states, so there may be milestones between the regions and states.

iii. How is EPA communicating with the impacted communities around these facilities?

(b) (5)

iv. Could we get the schedule of meetings you had with public affairs directors from each region in the month leading up to the public release of the 2014 NATA?

Yes, I can provide that to you. [Evaluator note: After the meeting, (b) (6) provided us with the schedule. See Source B. Acronyms used in Source B include:

NATA = National Air Toxics Assessment

OCIR = Office of Congressional and Intergovernmental Relations

PADs = Public Affairs Directors]

g. With respect to addressing the high-risk ethylene oxide facilities or any other ethylene oxide facilities, are regions allowed to:

i. Issue CAA Section 114 letters to facilities? If not, why not?

(b) (5)

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Renee McGhee-Lenart	6/14/19
No comments.	

- ii. Conduct inspections or take enforcement actions? If not, why not?

(b) (5)

- iii. Conduct modeling on their own? If not, why not?

(b) (5)

- iv. Conduct monitoring? If not, why not?

(b) (5)

#### Rollout of Region 5's Sterigenics Webpage

6. We understand that in preparation for the 2014 NATA rollout, Region 5 also prepared a desk statement and webpage on Sterigenics. We understand that you had reviewed Region 5's draft desk statement on Sterigenics. We also understand that Region 5's webpage on Sterigenics was rolled out at the same time as the 2014 NATA webpage on August 22, 2018. The Sterigenics webpage went live for about an hour before HQ ordered the webpage to be pulled down.

(b) (5)

- a. Do you know why Region 5's Sterigenics webpage pulled down?

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Renee McGhee-Lenart	6/14/19
No comments.	



(b) (5)

(b) (5)

- b. We also understand that Region 5 had planned to release its May 2018 monitoring results for Sterigenics back in June 2018 – two months prior to August 2018. Do you know why HQ did not approve the release of the May 2018 monitoring data?

(b) (5)

#### Communications with the Public and Facilities

7. We understand that HQ and OAQPS have taken over as the lead when communicating with the public and facilities about ethylene oxide in Region 5. Is this correct? If so, when did this happen? Why did HQ believe this was needed?

(b) (5), (b) (6)

8. Were you involved with communication with Sterigenics? If so, how did you communicate with the public who lived in the area? Was the public receptive to the communication?

(b) (6), (b) (5)

9. Are you involved with communicating with communities other than Willowbrook that have ethylene oxide emitting facilities in their area? If so, please describe.

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Renee McGhee-Lenart	6/14/19
No comments.	

(b) (5), (b) (6)

10. Are you aware of any EPA regulations, policies, or procedures that would require the Agency to communicate health risks to the public?

(b) (5)

11. Do you have knowledge of the following HQ directives or heard of the following HQ directives?

- Directive not to do inspections at ethylene oxide facilities.

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Bao Chuong	6/13/19
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Renee McGhee-Lenart	6/14/19
No comments.	

(b) (5)

- Directive not to do monitoring at ethylene oxide facilities.

(b) (5)

- Directive not to do modeling at ethylene oxide facilities.

(b) (5)

- Directive for Region 5 not to work with ATSDR.

(b) (5)

- Directive not to release the May 2018 monitoring data at Sterigenics in June 2018.

(b) (5)

- Directive not to send 114 letters to ethylene oxide facilities.

(b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/13/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/14/19
No comments.	

Reviewer Comment (and Date of Review)	Team Response (and Date of Response)	Resolution (and Date of Resolution)
No comments.  RML 6/14/19		WP approved.  RML 6/14/19

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/13/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/14/19
No comments.	

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.02.ac**

**PURPOSE:** To interview (b) (6) regarding EPA's role in addressing ethylene oxide and chloroprene emissions.

**SCOPE:** Interviewed (b) (6) regarding EPA's role in addressing ethylene oxide and chloroprene emissions.

**SOURCE:** A) See list of participants below.

**DATE and TIME:** 7/15/19, 10:00 – 11:30 AM CDT.

**LOCATION:** OIG Conference Room in Dallas, TX

**PARTICIPANTS:**

(b) (6)

OIG – Office of Audit and Evaluation – Air Directorate  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy points from the interview included:

- (b) (5), (b) (6)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	7/29/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	7/30/2019

- (b) (5)

**DETAILS:**

After introductions, Renee provided background information on our assignment. She explained that this is a two-part assignment. Initially, we sent out a notification memo with an objective to determine whether EPA's residual risk and technology review process has sufficiently identified and addressed any elevated cancer risks from air toxics emitted by facilities. We then received four Congressional requests related to ethylene oxide. Our management decided to have us address the four Congressional requests. We have decided that we will write a report to address the four Congressional requests.

As a result of the four Congressional requests, we have expanded the scope to address the following Congressional questions:

- Whether EPA senior political appointees instructed EPA inspectors to avoid conducting inspections at EtO emitting facilities across EPA Regions 5 and 6.
- Have inspections by the EPA been conducted on [ethylene oxide-emitting] facilities in Regions 5 and 6? If not, why?
- Whether the EPA complied with all statutory, regulatory and policy requirements and protocols in disclosing public health information about ethylene oxide air emissions from the Sterigenics facility in DuPage County, Illinois, the Medline Industries, Inc. facility in Lake County, Illinois and the Vantage Specialty Chemicals, Inc. facility in Lake County, Illinois.

After providing the background, Renee then proceeded to ask the following questions. (b) (6)  
response is in blue text.

Background on (b) (6)

1. What is your title or role?

(b) (6)

2. How long have you been in your current position?

(b) (6)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	7/29/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	7/30/2019

3. Who do you report to?

I report to (b) (6).

#### HQ Directives

4. Do you have knowledge of the following HQ directives or heard of the following HQ directives?

- Directive not to conduct inspections at ethylene oxide facilities.

(b) (5), (b) (6).

- Directive not to conduct monitoring at ethylene oxide facilities.

(b) (5), (b) (6)

- Directive not to do modeling at ethylene oxide facilities.

(b) (5), (b) (6).

- Directive not to send 114 letters to ethylene oxide facilities.

(b) (5), (b) (6).

#### Section 114 Letter to Denka

5. We understand that on December 18, 2015, EPA sent a 114 letter to Denka to obtain information necessary to determine compliance with the Clean Air Act, the emissions inventory requirements of the Louisiana SIP, and the facility permit. Subsequently, NEIC, along with 3 Region 6 air inspectors and an LDEQ inspector, conducted an onsite inspection of Denka from June 6 – 10, 2016.

- a. Similarly, has Region 6 sent a 114 letter to any ethylene oxide facilities in the region? If not, why not?

(b) (5)

(b) (5), (b) (6)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	7/29/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	7/30/2019

- b. Similarly, does Region 6 plan to inspect any of the ethylene oxide facilities in the region?  
If not, why not?

(b) (5), (b) (6)

#### Onsite Visit of Denka May 18, 2016

6. We understand that OAQPS conducted a site visit of Denka on May 28, 2016 to gather information on the processes and air pollution controls at the facility.
- a. Did you participate in the site visit? If so, please provide a high-level overview of what was found.

(b) (5), (b) (6)

- b. Do you know whether any of the information found will be used in a potential new risk and technology review?

(b) (5), (b) (6)

#### Current NESHAP for Group I Polymers and Resins

7. Do you think the current NESHAP for Group 1 polymers and resins is protective of human health? If not, what existing standards need to be revised or what new standards need to be implemented?

(b) (5)

#### Onsite Inspection of Denka June 6-10, 2016

8. We understand that EPA's NEIC conducted an onsite inspection of Denka from June 6 to June 10, 2016, and that three Region 6 air inspectors (b) (6) and one LDEQ inspector participated in the inspection. (b) (6)

(b) (6)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	7/29/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	7/30/2019



9. Please provide a high-level overview of the inspection findings.

(b) (5)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	7/29/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	7/30/2019

(b) (5) [Redacted text block]

(b) (5) [Redacted text block]

Prepared by:	Date
Bao Chuong	7/29/19
Approved by:	Date
Renee McGhee-Lenart	7/30/2019

(b) (5)

10. Did the inspection result in any enforcement actions taken against Denka? If so, please elaborate.

[See response to Question 9.](#)

11. Has NEIC, Region 6, or LDEQ conducted another inspection to verify that violations have been corrected? If so, when did the inspection take place and has Denka corrected all violations?

(b) (5)

12. Have there been times since January 2017 when you or someone else in Region 6 wanted to conduct an onsite inspection at Denka or other facilities but was told not to? If so, please elaborate.

(b) (5)

13. Have there been times since January 2017 when you or someone else in Region 6 wanted to send a 114 letter to Denka or other facilities but was told not to? If so, please elaborate.

(b) (5)

Prepared by:	Date
Bao Chuong	7/29/19
Approved by:	Date
Renee McGhee-Lenart	7/30/2019

14. Have there been times since January 2017 when you or someone else in Region 6 wanted to take an enforcement action against Denka or other facilities but was told not to? If so, please elaborate.

(b) (5)

15. Have there been times since January 2007 when you or someone else in Region 6 wanted Denka to conduct its own monitoring, such as monitoring for fugitive emissions? Please elaborate.

(b) (5)

#### State Inspections

16. Has LDEQ conducted onsite inspections of Denka since June 2016?

(b) (5)

(b) (5)

(b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	7/29/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	7/30/2019

<b>Reviewer Comment (and Date of Review)</b>	<b>Team Response (and Date of Response)</b>	<b>Resolution (and Date of Resolution)</b>
No comments. RML 7/30/2019		WP approved. RML 7/30/2019

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	7/29/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	7/30/2019

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.02.ad**

**PURPOSE:** Obtain information regarding Region 6's role in addressing ethylene oxide and chloroprene emissions from stationary sources.

**SCOPE:** This workpaper summarizes an interview with (b) (6), of EPA Region 6, to obtain information about (b) (6) knowledge of how EPA Region 6 works to address ethylene oxide and chloroprene emissions.

**SOURCE:** See the list of meeting participants below.

**DATE and TIME:** 7/16/19, 10:00am – 11:30am CDT.

**LOCATION:** Region 6 Office in Dallas, TX, (b) (6).

**PARTICIPANTS:**

**Link:** WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docxRegion 6 (b) (6)

**OIG – Office of Audit and Evaluation – Air Directorate**

Renee McGhee-Lenart, Project Manager, (913) 551-7534

Bao Chuong, Physical Scientist, (415) 947-4533

Andrew Lavenburg, Social Scientist, (919) 541-1871 (participated in meeting via telephone)

**CONCLUSION:** No conclusions drawn from this one meeting.

**DETAILS:**

Prior to the interview, Ms. McGhee-Lenart provided some background on the OIG audit, explained the audit objective, and also provided the key questions that members of Congress had ask OIG to evaluate.

Questions asked by OIG during the interview are in black font, below, with a summary of the discussion in response to each question provided in blue font.

<b>Prepared by:</b>	<b>Date</b>
Andrew Lavenburg	7/29/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	8/01/2019

Background on (b) (6)

1. What is your title or role?

(b) (6)

(b) (6)

2. How long have you been in your current position?

(b) (6).

3. Who do you report to?

(b) (6)

#### HQ Directives

4. Do you have knowledge of the following HQ directives or heard of the following HQ directives?

- Directive not to conduct inspections at ethylene oxide facilities.

(b) (5)

Prepared by:	Date
Andrew Lavenburg	7/29/19
Approved by:	Date
Renee McGhee-Lenart	8/01/2019

- Directive not to conduct monitoring at ethylene oxide facilities.

(b) (5)

(b) (5), (b) (6)

- Directive not to do modeling at ethylene oxide facilities.

(b) (5)

- Directive not to send 114 letters to ethylene oxide facilities.

(b) (5)

### OAR's Two-Pronged Approach to Address Ethylene Oxide-Emitting Facilities

5. As you may know, OAR developed and rolled out a two-pronged approach to address ethylene oxide-emitting facilities. Prong 1 is rulemaking, such as issuing RTR rules. What have you heard about Prong 2? For example, what are the goals and milestones for Prong 2?

[Link: WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docx](#) Prong 2,

(b) (5), (b) (6)

Prepared by:	Date
Andrew Lavenburg	7/29/19
Approved by:	Date
Renee McGhee-Lenart	8/01/2019



(b) (5), (b) (6)

[Link: WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docx](#)Ms. McGhee-Lenart asked if EPA Headquarters had communicated any goals or milestones to the Region related to Prong 2. (b) (5), (b) (6)

Ms. McGhee-Lenart asked if the follow-up was that for anything that was considered high risk from the 2014 NATA data. (b) (5), (b) (6)

#### High-Risk Ethylene Oxide-Emitting Facilities in Region 6


6. We understand that during the development of the 2014 NATA, OAQPS sent drafts of NATA to states and regions for review.
  - a. After reviewing the 2014 NATA drafts, did Region 6 conduct its own air quality dispersion modeling of ethylene oxide facilities?

(b) (5), (b) (6)
  - b. Did Region 6 reach out to facilities to confirm the emissions data being used for the 2014 NATA development?

(b) (5)
  - i. If so, which facilities and were they responsive to Region 6's outreach?

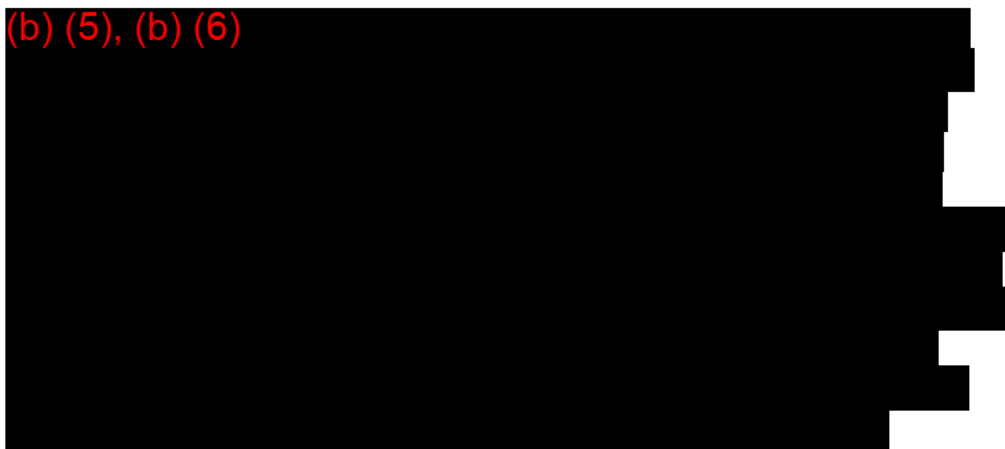
Prepared by:	Date
Andrew Lavenburg	7/29/19
Approved by:	Date
Renee McGhee-Lenart	8/01/2019

(b) (5), (b) (6)




- ii. At any time, did you consider sending 114 letters to any of the facilities to confirm or obtain emissions data? If so, for which facilities? Did you send any 114 letters to these facilities? If not, why not?

(b) (5), (b) (6)



- c. Did the region conduct any other activities to confirm the preliminary 2014 NATA emissions data?

(b) (5), (b) (6)


Prepared by:	Date
Andrew Lavenburg	7/29/19
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Renee McGhee-Lenart	8/01/2019

(b) (5), (b) (6)

7. We understand that OAQPS developed a list of high-risk ethylene oxide-emitting facilities that regions are to focus on.

- a. What criteria was used to develop the list of facilities?

(b) (5), (b) (6)

- b. What are OAQPS' expectations of the regions with respect to the high-risk facilities?

(b) (5), (b) (6)

- c. What are Region 6's plans with regards to the high-risk facilities?

(b) (5), (b) (6)

Ms. McGhee-Lenart asked who would know the most about this. (b) (5), (b) (6)

- d. Are there any milestone dates associated with regional activities at the high-risk facilities?

(b) (5)

- e. Since the release of the 2014 NATA to the public,

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Andrew Lavenburg	7/29/19
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Renee McGhee-Lenart	8/01/2019

i. How many of the high-risk facilities has Region 6 communicated with?

(b) (5), (b) (6) (b) (5)

ii. What actions has Region 6 taken with respect to the high-risk facilities?

(b) (5), (b) (6)

iii. What voluntary reductions, if any, has Region 6 pursued with the 10 high-risk facilities?

(b) (5), (b) (6)

iv. Are there any plans to inspect any of the 10 high-risk facilities? Why or why not?

(b) (5), (b) (6)

f. (b) (5)

(b) (5)

(b) (6) said that (b) (6) doesn't know. (b) (5)

ii. (b) (5)

Due to the answer given above, we did not ask this question during interview.

g. We understand that the 2014 NATA shows census tracts around Denka having total cancer risks attributed to both chloroprene and ethylene oxide emissions. Which of the high-risk ethylene oxide facilities is responsible for the high cancer

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Andrew Lavenburg	7/29/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	8/01/2019

risks in St. John the Baptist Parrish, Louisiana? Has Region 6 informed the community of the higher cancer risks due to both chloroprene and ethylene oxide emissions?

(b) (5), (b) (6)

(b) (5)

Ms. McGhee-Lenart asked who did that outreach. (b) (6)

- h. We understand that on December 18, 2015, EPA sent a 114 letter to Denka to obtain information necessary to determine compliance with the Clean Air Act, the emissions inventory requirements of the Louisiana SIP, and the facility permit. Subsequently, NEIC, along with 3 Region 6 air inspectors and an LDEQ inspector, conducted an onsite inspection of Denka from June 6 – 10, 2016.
- i. Similarly, has Region 6 sent a 114 letter to any ethylene oxide facilities in the region? If not, why not?

(b) (5), (b) (6) (b) (5)

- ii. Similarly, does Region 6 plan to inspect any of the ethylene oxide facilities in the region? If not, why not?

(b) (5), (b) (6) (b) (5), (b) (6)

(b) (5)

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Andrew Lavenburg	7/29/19
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Renee McGhee-Lenart	8/01/2019

8. We understand there's (b) (5)

s?

(b) (5), (b) (6)

#### Public Outreach in Communities Where the High-Risk Facilities Are Located

9. Does EPA have to follow any statutory, regulatory, and/or policy requirements and protocols to disclose public health information about emissions of hazardous air pollutants, such as ethylene oxide and chloroprene?

(b) (5), (b) (6)

10. Regarding (b) (5) high-risk ethylene oxide facilities in Region 6,

a. How many communities (i.e., town/city where facility is located) has Region 6 reached out to about the 2014 NATA results?

(b) (5), (b) (6)

b. By what means (e.g., public meetings, webinars) has Region 6 reached out to the communities?

(b) (5), (b) (6)

c. How have the communities reacted to Region 6's outreach efforts?

(b) (5), (b) (6)

Ms. McGhee-Lenart asked how the community around Denka was doing. She asked if the issue involving the facility's emissions was still a contentious one in the community. (b) (5), (b) (6)

<b>Prepared by:</b>	<b>Date</b>
Andrew Lavenburg	7/29/19
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Renee McGhee-Lenart	8/01/2019

(b) (5)

- d. Has Region 6 reached out to advocacy groups where (b) (5) s are located? If so, which ones? What has been their response?

(b) (5), (b) (6)

- e. Has Region 6 reached out to elected officials where (b) (5) ethylene oxide facilities are located? If so, which ones? What has been their response?

(b) (5), (b) (6)

- f. What needs or requests have communities, advocacy groups, and elected officials asked of Region 6? Has Region 6 been able to meet their needs or requests?

(b) (5), (b) (6)

- g. We understand that an action plan was prepared to inform interested parties and report the status of planned and in-progress activities to address NATA data, chloroprene emissions from Denka, and community concerns about these emissions. Have action plans been developed for the ethylene oxide facilities in Region 6?

(b) (5), (b) (6)

### Ambient Monitoring Around Ethylene Oxide Facilities

11. We understand that one of the reasons EPA conducted ambient monitoring around Denka was to determine whether the levels of chloroprene found in the 2011 NATA were indeed present in the air. Similarly, does Region 6 have any plans to conduct ambient monitoring in communities surrounding (b) (5) ethylene oxide-emitting facilities in the region? Why or why not?

<b>Prepared by:</b>	<b>Date</b>
Andrew Lavenburg	7/29/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	8/01/2019

(b) (5), (b) (6)

## IRIS Assessments

12. Prior to the development of the 2011 NATA by OAQPS, were you aware that the IRIS program issued a new IRIS assessment for chloroprene in September 2010?

(b) (5), (b) (6)

13. Prior to the development of the 2014 NATA by OAQPS, were you aware that the IRIS program issued a new IRIS assessment for ethylene oxide in December 2016?

(b) (5), (b) (6)

Ms. McGhee-Lenart said that it seemed that the change was more widely known once NATA was released, and not when the change from the assessment was actually done.

(b) (5), (b) (6)

Reviewer Comment (and Date of Review)	Team Response (and Date of Response)	Resolution (and Date of Resolution)
No comments.  RML 8/1/19		WP approved.  RML 8/1/2019

Prepared by:	Date
Andrew Lavenburg	7/29/19
Approved by:	Date
Renee McGhee-Lenart	8/01/2019



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<b>Prepared by:</b>	<b>Date</b>
Andrew Lavenburg	7/29/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	8/01/2019

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.02.ae**

**PURPOSE:** Obtain information regarding Region 6's role in addressing ethylene oxide and chloroprene emissions from stationary sources.

**SCOPE:** This workpaper summarizes an interview with (b) (6), of EPA Region 6, to obtain information about (b) (6) knowledge of how EPA Region 6 works to address ethylene oxide and chloroprene emissions.

**SOURCE:** See the list of meeting participants below.

**DATE and TIME:** 7/16/19, 12:30pm – 1:30pm CDT.

**LOCATION:** Region 6 Office in Dallas, TX, Conference Room (b) (5)

**PARTICIPANTS:**

**Region 6**

(b) (6)

**OIG – Office of Audit and Evaluation – Air Directorate**

Renee McGhee-Lenart, Project Manager, (913) 551-7534

Bao Chuong, Physical Scientist, (415) 947-4533

Andrew Lavenburg, Social Scientist, (919) 541-1871 (participated in meeting via telephone)

**CONCLUSION:** No conclusions drawn from this one meeting.

**DETAILS:**

Prior to the interview, Ms. McGhee-Lenart provided some background on the OIG audit, explained the audit objective and also provided the key questions that members of Congress had ask OIG to evaluate.

Questions asked by OIG during the interview are in black font, below, with a summary of the discussion in response to each question provided in blue font.

**Background on (b) (6)**

1. What is your title or role?

(b) (6) said that (b) (6)

. (b) (6)

(b) (6) (b) (5), (b) (6)

2. How long have you been in your current position?

(b) (6)

3. Who do you report to?

(b) (6)

#### HQ Directives

4. Do you have knowledge of the following HQ directives or heard of the following HQ directives?

- Directive not to conduct inspections at ethylene oxide facilities.

(b) (5), (b) (6)

- Directive not to conduct monitoring at ethylene oxide facilities.

(b) (5), (b) (6)

- Directive not to do modeling at ethylene oxide facilities.

(b) (5), (b) (6)

- Directive not to send 114 letters to ethylene oxide facilities.

(b) (5), (b) (6)

#### Section 114 Letter to Denka

5. We understand that on December 18, 2015, EPA sent a 114 letter to Denka to obtain information necessary to determine compliance with the Clean Air Act, the emissions inventory requirements of the Louisiana SIP, and the facility permit. Subsequently, NEIC, along with 3 Region 6 air inspectors and an LDEQ inspector, conducted an onsite inspection of Denka from June 6 – 10, 2016.

- a. Similarly, has Region 6 sent a 114 letter to any ethylene oxide facilities in the region? If not, why not?

(b) (5), (b) (6)

- b. Similarly, does Region 6 plan to inspect any of the ethylene oxide facilities in the region? If not, why not?

(b) (5), (b) (6)

#### Onsite Visit of Denka May 18, 2016

6. We understand that OAQPS conducted a site visit of Denka on May 18, 2016 to gather information on the processes and air pollution controls at the facility.
- a. Did you participate in the site visit? If so, please provide a high-level overview of what was found.

(b) (5), (b) (6)

- b. Do you know whether any of the information found will be used in a potential new risk and technology review?

Due to the response to question 6.a, this question was not asked during the interview.

#### Current NESHAP for Group I Polymers and Resins

7. Do you think the current NESHAP for Group 1 polymers and resins is protective of human health? If not, what existing standards need to be revised or what new standards need to be implemented?

(b) (5), (b) (6)

(b) (5), (b) (6)

#### Onsite Inspection of Denka June 6-10, 2016

8. We understand that EPA's NEIC conducted an onsite inspection of Denka from June 6 to June 10, 2016, and that three Region 6 air inspectors (b) (6) and one LDEQ inspector participated in the inspection. Did you assist with the inspection or did you just observe the inspection?

(b) (6)

9. Please provide a high-level overview of the inspection findings.

(b) (5), (b) (6) the onsite inspection started on 6/6/16, and the onsite portion of the inspection was completed on 6/10/16. (b) (5), (b) (6):

- (b) (5), (b) (6)

(b) (5), (b) (6)

Ms. McGhee-Lenart asked if (b) (6) attended a closeout meeting after the inspection. (b) (5), (b) (6)

(b) (5), (b) (6)

- (b) (5), (b) (6)

(b) (5), (b) (6)

Mr. Chuong asked if the LDAR was used to monitor chloroprene (b) (5), (b) (6)

Mr. Chuong asked what was meant by (b) (5), (b) (6)

10. Did the inspection result in any enforcement actions taken against Denka? If so, please elaborate.

(b) (5), (b) (6)

11. Has NEIC, Region 6, or LDEQ conducted another inspection to verify that violations have been corrected? If so, when did the inspection take place and has Denka corrected all violations?

(b) (5), (b) (6)

12. If Denka has corrected all violations, has ambient concentrations of chloroprene decreased to the point that it's not resulting in a 100-in-1 million cancer risk?

This question was not asked during the interview.

13. Have there been times since January 2017 when you or someone else in Region 6 wanted to conduct an onsite inspection at Denka or other facilities but was told not to? If so, please elaborate.

(b) (5), (b) (6)

14. Have there been times since January 2017 when you or someone else in Region 6 wanted to send a 114 letter to Denka or other facilities but was told not to? If so, please elaborate.

(b) (5), (b) (6)

15. Have there been times since January 2017 when you or someone else in Region 6 wanted to take an enforcement action against Denka or other facilities but was told not to? If so, please elaborate.

(b) (5), (b) (6)

16. Have there been times since January 2017 when you or someone else in Region 6 wanted Denka to conduct its own monitoring, such as monitoring for fugitive emissions? Please elaborate.

(b) (5), (b) (6)

#### State Inspections

17. Has LDEQ conducted onsite inspections of Denka since June 2016?

(b) (5), (b) (6)

a. If so, when were the state inspections?

Not asked, due to response to Question 17.

b. Did you or anyone else from Region 6 participate in the inspections?

Not asked, due to response to Question 17.

c. Did LDEQ take any enforcement actions? If so, please elaborate.

Not asked, due to response to Question 17.

(b) (5)

18. We understand that (b) (5)

(b) (5), (b) (6)

(b) (5), (b) (6)

(b) (5), (b) (6)

[Redacted]

Mr. Chuong asked if the Region is required to get approval from OAQPS before issuing 114 letters (b) (5), (b) (6)

[Redacted]

(b) (5)

[Redacted]

(b) (5)

[Redacted]

Preparer's Initials and Date	
AJL	7/29/19

Reviewer Comment (and Date of Review)	Team Response (and Date of Response)	Resolution (and Date of Resolution)
No comments.		WP approved.
RML 8/14/19		RML 8/14/19



**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.02.af**

**PURPOSE:** To interview (b) (6) regarding EPA's role in addressing ethylene oxide and chloroprene emissions.

**SCOPE:** Interviewed (b) (6) regarding EPA's role in addressing ethylene oxide and chloroprene emissions.

**SOURCE:** A) Region 6 ethylene oxide strategic plan, 3/20/19 (Received from (b) (6) on 8/21/19)

B) Forwarded email from (b) (6) with a link for the public to comment on TCEQ's ethylene oxide carcinogenic dose-response assessment proposed development support document (Received from (b) (6) on 8/21/19).

C) See list of participants below.

**DATE and TIME:** 7/16/19, 3:30 – 5:45 PM CDT.

**LOCATION:** Region 6 Conference Room (b) (6) Dallas, TX

**PARTICIPANTS:**

[Link:](#) WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach (b) (6)

(b) (6)

OIG – Office of Audit and Evaluation – Air Directorate  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy points from the interview included:

- (b) (5), (b) (6)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	8/30/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	9/03/2019

- (b) (5), (b) (6) [REDACTED]

**DETAILS:**

(b) (6), Renee asked whether (b) (6) needed some background on the audit or whether we can start asking questions. (b) (6) responded that (b) (6) was fine with jumping into the questions.

Renee began asking the following questions. (b) (6)' responses are in blue text.

Background on (b) (6)

1. What is your title or role?

(b) (6) [REDACTED]

2. How long have you been in your current position?

(b) (6) [REDACTED]

3. Who do you report to?

(b) (6) [REDACTED]

**HQ Directives**

4. Do you have knowledge of the following HQ directives or heard of the following HQ directives?

- Directive not to conduct inspections at ethylene oxide facilities. (b) (5) [REDACTED]

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	8/30/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	9/03/2019

- Directive not to conduct monitoring at ethylene oxide facilities. (b) (5)

- Directive not to do modeling at ethylene oxide facilities. (b) (5)

- Directive not to send 114 letters to ethylene oxide facilities. (b) (5)

#### OAR's Two-Pronged Approach to Address Ethylene Oxide-Emitting Facilities

5. As you may know, OAR developed and rolled out a two-pronged approach to address ethylene oxide-emitting facilities. Prong 1 is rulemaking, such as issuing RTR rules. What have you heard about Prong 2? For example, what are the goals and milestones for Prong 2?

[Link: WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docx](#) Prong 2 deals primarily with actions within Region 6. We are to work with states on ethylene oxide-emitting facilities. We provide information about risks associated with a facility's ethylene oxide emissions to the states.



(b) (5)

(b) (5)

(b) (5)

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<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	9/03/2019

(b) (5)



[Source B is the forwarded email providing a link to the public to comment on TCEQ's ethylene oxide carcinogenic dose-response assessment proposed development support document.]

6. We understand that prior to the release of the 2014 NATA to the public, there was a workgroup led by Regions 2 and 5 that met to discuss ethylene oxide issues. This regional-led group was terminated after the release of the 2014 NATA and replaced with a commercial sterilizers workgroup and a chemical plants workgroup. More recently, these two workgroups have been terminated and replaced with the OAQPS-led "ethylene oxide coordination calls." Have you participated in the workgroup or ethylene oxide coordination calls? If so, what was discussed in the workgroups and calls?

(b) (5), (b) (6)



(b) (5)

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Renee McGhee-Lenart	9/03/2019

(b) (5)

Region 6 has some of the facilities' permits [here](#). Louisiana permits are online.

(b) (5)

(b) (5)

#### High-Risk Ethylene Oxide-Emitting Facilities in Region 6

7. We understand that during the development of the 2014 NATA, OAQPS sent drafts of NATA to states and regions for review.
  - a. After reviewing the 2014 NATA drafts, did Region 6 conduct its own air quality dispersion modeling of ethylene oxide facilities?

(b) (5), (b) (6)

- b. Did Region 6 reach out to facilities to confirm the emissions data being used for the 2014 NATA development?

(b) (5)

- i. If so, which facilities and were they responsive to Region 6's outreach?

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Renee McGhee-Lenart	9/03/2019

(b) (5)

- ii. At any time, did you consider sending 114 letters to any of the facilities to confirm or obtain emissions data? If so, for which facilities? Did you send any 114 letters to these facilities? If not, why not?

(b) (5)

- c. Did the region conduct any other activities to confirm the preliminary 2014 NATA data?

(b) (5)

8. We understand that OAQPS developed a list of high-risk ethylene oxide-emitting facilities that regions are to focus on.

- a. What criteria was used to develop the list of facilities?

(b) (5)

- b. What are OAQPS' expectations of the regions with respect to the high-risk facilities?

(b) (5)

(b) (5)

- c. What are Region 6's plans with regards to the high-risk facilities?

(b) (5)

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(b) (5)

(b) (5)

One thing that has come out in December 2018 or January 2019 is monitoring data on trends in air toxics from the National Air Toxics Trends Station (NATTS) network. (b) (5)

(b) (5)

- d. Are there any milestone dates associated with regional activities at the high-risk facilities?

[Link: WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docx](#) (b) (5)

(b) (5)

(b) (5)

(b) (5)

(b) (5)

(b) (5)

(b) (5)

[Source A is the Region 6 ethylene oxide strategic plan that (b) (6) provided on 8/21/19.]

- e. Since the release of the 2014 NATA to the public,

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i. How many of the high-risk facilities has Region 6 communicated with?

(b) (5)

ii. What actions has Region 6 taken with respect to the high-risk facilities?

See response to 8e.i.

iii. What voluntary reductions, if any, has Region 6 pursued with (b) (5) ?

See response to 8e.i.

iv. Are there any plans to inspect any of the (b) (5) ? Why or why not?

(b) (5)

f. We understand that (b) (5)

(b) (5)

(b) (5)

ii. Do you agree with (b) (5) ? Why or why not?

Did not ask. See response to 8f.i.

Prepared by:	Date
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- g. We understand that the 2014 NATA shows census tracts around Denka having total cancer risks attributed to both chloroprene and ethylene oxide emissions. Which of the high-risk ethylene oxide facilities is responsible for the high cancer risks in St. John the Baptist Parrish, Louisiana? Has Region 6 informed the community of the higher cancer risks due to both chloroprene and ethylene oxide emissions?

(b) (5)

- h. We understand that on December 18, 2015, EPA sent a 114 letter to Denka to obtain information necessary to determine compliance with the Clean Air Act, the emissions inventory requirements of the Louisiana SIP, and the facility permit. Subsequently, NEIC, along with 3 Region 6 air inspectors and an LDEQ inspector, conducted an onsite inspection of Denka from June 6 – 10, 2016.

- i. Similarly, has Region 6 sent a 114 letter to any ethylene oxide facilities in the region? If not, why not?

See response to 7b.ii.

- ii. Similarly, does Region 6 plan to inspect any of the ethylene oxide facilities in the region? If not, why not?

See response to 8c.

(b) (5)

(b) (5), (b) (6)

#### Public Outreach in Communities Where the High-Risk Facilities Are Located

10. Does EPA have to follow any statutory, regulatory, and/or policy requirements and protocols to disclose public health information about emissions of hazardous air pollutants, such as ethylene oxide and chloroprene? Not aware of statutes or regulations. Not aware of policy requirements. Protocols in Region 6 – which is to keep community informed, but it is not written down. Because of dealing with Superfund, don't keep this information quiet.

We have guidelines on communications – who to contact, what the message is, how do we communicate the message, etc. We get a list of environmental justice (EJ) groups and environmental advocacy groups.

Prepared by:	Date
Bao Chuong	8/30/19
Approved by:	Date
Renee McGhee-Lenart	9/03/2019

(b) (5)

11. Regarding the (b) (5) in Region 6,

- a. How many communities (i.e., town/city where facility is located) has Region 6 reached out to about the 2014 NATA results?

(b) (5)

- b. By what means (e.g., public meetings, webinars) has Region 6 reached out to the communities?

(b) (5)

- c. How have the communities reacted to Region 6's outreach efforts?

Did not ask. See response to 11a and 11b.

- d. Has Region 6 reached out to advocacy groups (b) (5) If so, which ones? What has been their response?

(b) (5)

- e. Has Region 6 reached out to elected officials where (b) (5) If so, which ones? What has been their response?

(b) (5), (b) (6)

- f. What needs or requests have communities, advocacy groups, and elected officials asked of Region 6? Has Region 6 been able to meet their needs or requests?

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	8/30/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	9/03/2019

(b) (5)

- g. We understand that an action plan was prepared to inform interested parties and report the status of planned and in-progress activities to address NATA data, chloroprene emissions from Denka, and community concerns about these emissions. Have action plans been developed for the ethylene oxide facilities in Region 6?

(b) (5)

#### Ambient Monitoring Around Ethylene Oxide Facilities

12. We understand that one of the reasons EPA conducted ambient monitoring around Denka was to determine whether the levels of chloroprene found in the 2011 NATA were indeed present in the air. Similarly, does Region 6 have any plans to conduct ambient monitoring in communities surrounding (b) (5) facilities in the region? Why or why not?

(b) (5)

#### IRIS Assessments

13. Prior to the development of the 2011 NATA by OAQPS, were you aware that the IRIS program issued a new IRIS assessment for chloroprene in September 2010?

(b) (5)

14. Prior to the development of the 2014 NATA by OAQPS, were you aware that the IRIS program issued a new IRIS assessment for ethylene oxide in December 2016?

(b) (5) (b) (5)

(b) (5)

<b>Prepared by:</b>	<b>Date</b>
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Renee McGhee-Lenart	9/03/2019

(b) (5)

Reviewer Comment (and Date of Review)	Team Response (and Date of Response)	Resolution (and Date of Resolution)
No comments. RML 9/03/19		WP approved. RML 9/03/19

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	8/30/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	9/03/2019

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP 02.ag**

**PURPOSE:** Obtain information regarding Region 6's role in addressing ethylene oxide and chloroprene emissions from stationary sources.

**SCOPE:** This workpaper summarizes an interview with (b) (6), of EPA Region 6, to obtain information about (b) (6) knowledge of how EPA Region 6 works to address ethylene oxide and chloroprene emissions.

**SOURCE:** See the list of meeting participants below.

**DATE and TIME:** 7/17/19, 12:30pm – 1:30pm CDT.

**LOCATION:** Region 6 Office in Dallas, TX, Conference Room (b) (6)

**PARTICIPANTS:**

**Region 6**

(b) (6)

**OIG – Office of Audit and Evaluation – Air Directorate**

Renee McGhee-Lenart, Project Manager, (913) 551-7534

Bao Chuong, Physical Scientist, (415) 947-4533

Andrew Lavenburg, Social Scientist, (919) 541-1871 (participated in meeting via telephone)

**CONCLUSION:** No conclusions drawn from this one meeting.

**DETAILS:**

Prior to the interview, Ms. McGhee-Lenart provided some background on the OIG audit, explained the audit objective, and also provided the key questions that members of Congress had ask OIG to evaluate.

Questions asked by OIG during the interview are in black font, below, with a summary of the discussion in response to each question provided in blue font.

**Background on (b) (6)**

1. What is your title or role?

(b) (6)

(b) (6)

2. How long have you been in your current position?

(b) (6)

3. Who do you report to?

(b) (6)

#### HQ Directives

4. Do you have knowledge of the following HQ directives or heard of the following HQ directives?

- Directive not to conduct inspections at ethylene oxide facilities.

(b) (5), (b) (6)

- Directive not to conduct monitoring at ethylene oxide facilities.

(b) (5), (b) (6)

- Directive not to do modeling at ethylene oxide facilities.

(b) (5), (b) (6)

- Directive not to send 114 letters to ethylene oxide facilities.

(b) (5), (b) (6)

## Requirements to Disclose Health Information to the Public

5. Does EPA have any statutory, regulatory, and/or policy requirements and protocols to disclose public health information about emissions of hazardous air pollutants, such as ethylene oxide and chloroprene?

(b) (5), (b) (6). The only requirement to disclose public health information about hazardous air pollutants that (b) (6) is aware of is the NATA, which he believes happens every five years.

Ms. McGhee-Lenart asked if there were any statues or regulations that require the agency to release public health information. (b) (6) said that the 40 CFR Part 63 NESHAPS are the regulations promulgated pursuant to Clean Air Act Section 112, which requires both the risk and technology reviews (b) (5), (b) (6)

[REDACTED]

Mr. Chuong asked for clarification about the requirement to conduct residual risk assessments. Mr. Chuong asked whether EPA would be required to conduct another residual risk assessment if an IRIS risk value had changed after an initial residual risk assessment had been performed for a MACT (i.e., would there be any requirement to conduct another residual risk assessment after 8 years if the risk value changed at some point after the initial residual risk assessment?). (b) (5), (b) (6)

[REDACTED]

[REDACTED]

[REDACTED]

(b) (5), (b) (6)

**(b) (6) Role With Respect to Denka**

6. What has been your role with respect to Denka?

(b) (5), (b) (6)

**CAA Section 114 Letter to Denka**

7. We understand that on December 18, 2015, Region 6 sent a 114 letter to Denka to obtain information necessary to determine compliance with the Clean Air Act, the emissions inventory requirements of the Louisiana SIP, and the facility permit. Subsequently, NEIC, along with 3 Region 6 air inspectors and an LDEQ inspector, conducted an onsite inspection of Denka from June 6 – 10, 2016.

- a. What was the driving force for sending the 114 letter to Denka?

(b) (5), (b) (6)

- b. Did Region 6 have to get approval from HQ or OAQPS to send the 114 letter to Denka?

(b) (5), (b) (6)



(b) (5), (b) (6)

- c. Was Denka responsive to the information request?

(b) (5), (b) (6)

- d. Had Region 6 ever sent a 114 letter to the former owner, DuPont? If so, what was the impetus for doing that?

(b) (5), (b) (6)

- e. Since the December 18, 2015 114 letter to Denka, have you or anyone else from Region 6 wanted to send another 114 letter? If so, was the 114 letter sent?

(b) (5), (b) (6)

- f. Have there been any cases in which Region 6 had to get approval from HQ or OAQPS to send a 114 letter?

(b) (5), (b) (6)

(b) (5), (b) (6)

- g. Has Region 6 sent a 114 letter to any ethylene oxide facilities in the region? If not, why not?

(b) (5), (b) (6)

- h. Does Region 6 plan to inspect any ethylene oxide facilities in the region? If not, why not?

(b) (5), (b) (6)

Preparer's Initials and Date	
AJL	7/29/19

Reviewer Comment (and Date of Review)	Team Response (and Date of Response)	Resolution (and Date of Resolution)
No comments. RML 8/14/19		WP approved. RML 8/14/19

Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources  
OA&E-FY19-0091  
WP H.02.ah

**PURPOSE:** To interview (b) (6) regarding EPA's role in addressing ethylene oxide emissions.

**SCOPE:** Interviewed (b) (6) regarding EPA's role in addressing ethylene oxide emissions.

**SOURCE:** A) EPA-OGC website showing the office leadership  
(<https://www.epa.gov/aboutepa/about-office-general-counsel-ogc>, accessed 7/24/19)

B) 11/21/18 OECA memo on best practices for compliance and enforcement-related information requests (received from (b) (6) on 7/17/19)

C) See list of participants below.

**DATE and TIME:** 7/17/19, 4:15 – 5:45 PM CDT.

**LOCATION:** Region 6 Conference Room (b) (6) Dallas, TX

**PARTICIPANTS:**

(b) (6)

OIG – Office of Audit and Evaluation – Air Directorate  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy points from the interview included:

- (b) (5), (b) (6)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	7/29/19
<b>Approved by:</b>	<b>Date</b>

o (b) (5), (b) (6)

**DETAILS:**

After introductions, Renee provided background information on our assignment. She explained that initially, we sent out a notification memo with an objective to determine whether EPA's residual risk and technology review process has sufficiently identified and addressed any elevated cancer risks from air toxics emitted by facilities. We then received four Congressional requests related to ethylene oxide. Our management decided to have us address the four Congressional requests. We have decided that we will write a report to address the four Congressional requests.

As a result of the four Congressional requests, we have expanded the scope to address the following Congressional questions:

- Whether EPA senior political appointees instructed EPA inspectors to avoid conducting inspections at EtO emitting facilities across EPA Regions 5 and 6.
- Have inspections by the EPA been conducted on [ethylene oxide-emitting] facilities in Regions 5 and 6? If not, why?
- Whether the EPA complied with all statutory, regulatory and policy requirements and protocols in disclosing public health information about ethylene oxide air emissions from the Sterigenics facility in DuPage County, Illinois, the Medline Industries, Inc. facility in Lake County, Illinois and the Vantage Specialty Chemicals, Inc. facility in Lake County, Illinois.

After providing the background, Renee then proceeded to ask the following questions. (b) (6) response is in blue text.

Background on (b) (6)

1. What is your title or role?

(b) (6)

2. How long have you been in your current position?

(b) (6)

Prepared by:	Date
Bao Chuong	7/29/19
Approved by:	Date

3. Who do you report to?

(b) (6)

4. (b) (6)

A [Link: Link:](#) (b) (6)

5. (b) (6)

(b) (6)

6. (b) (6)

(b) (6)

#### Requirements to Disclose Health Information to the Public

7. Does EPA have any statutory, regulatory, and/or policy requirements and protocols that requires it to disclose public health information about emissions of hazardous air pollutants, such as ethylene oxide and chloroprene?

(b) (5) Statutorily, there are reports that EPA is required to develop and issue.

(b) (5)

(b) (5) An RA makes policy decisions and decides on protocols. If an RA wants information to go out to the public, then the subordinate must disclose that information to the public.

(b) (5)

Prepared by:	Date
Bao Chuong	7/29/19
Approved by:	Date

In 2016 or 2017, there was a big public meeting regarding Denka and chloroprene emissions. (b) (6)

In Region 5, there were two public meetings on ethylene oxide and Sterigenics – one was in August 2018 and the other one in November 2018.

There were briefings to elected officials. Region 6 reached out to elected officials regarding chloroprene and Denka and answered their questions. In Region 5, there were a lot of calls to local officials regarding Sterigenics. There were also a lot of in-person meetings with elected officials on Sterigenics. Region 5 communicated with non-government organizations (NGOs) and advocacy groups on Sterigenics. Region 5 ended up responding to press questions a lot.

#### May 16 – 18, 2018 Monitoring of Sterigenics

8. We understand that Region 5, with assistance from OAQPS, conducted ambient monitoring around Sterigenics from May 16 – 18 in 2018. We were told that after the monitoring data were QA/QC'd, the Office of the Regional Administrator was briefed on the monitoring results on June 20, 2018. We understand that Regional Administrator Cathy Stepp directed the Air and Radiation Division and the Office of External Communications to prepare a website to post the monitoring results and a press release. We understand that two days later on June 22, 2018, there was a call between the Office of the Regional Administrator and OAR HQ. HQ told Region 5 not to post a website on Sterigenics and not to release the monitoring results.

(b) (5)

- a. Did you participate in the call with HQ on June 22, 2018? If so, who gave the directive not to prepare a website on Sterigenics and not to release the May 2018 monitoring results?

(b) (6)

Deputy Administrator Andrew Wheeler was on the call. In the call, (b) (5)

- b. If you did not participate in the call with HQ on June 22, 2018, who did you hear from about the directive not to prepare a website on Sterigenics and not to release the May 2018 monitoring results? Who did this person tell you who in HQ issued the directive?

N/A.

Prepared by:	Date
Bao Chuong	7/29/19
Approved by:	Date

9. (b) (6)

(b) (5), (b) (6)

#### August 22, 2018 Release of the 2014 NATA to the Public

10. We understand that the 2014 NATA was released to the public on August 22, 2018. The NATA website went live around noontime that day. We learned that the Region 5 website on Sterigenics along with the May 2018 monitoring results went live around the same time. However, we understand that OAR HQ ordered the Region 5 Sterigenics website taken down about an hour later.

- a. Were you aware of the HQ directive to take the Region 5 Sterigenics website down? If so, who in HQ ordered the website taken down?

(b) (5), (b) (6)

Evaluator note: Bao pointed out to (b) (6) that we were told that the website that came back up simply had a link to the ATSDR report. Other than that link, there was no other information on Sterigenics or the monitoring that was conducted.]

- b. Why was Region 5 directed to take down the Sterigenics website?

I don't know.

- c. What are your thoughts on the directive to take down the Region 5 Sterigenics website?

(b) (5)

#### Directive Not to Work With ATSDR

11. We were told that OAR HQ told Region 5 to no longer work with ATSDR or seek their assistance.

Prepared by:	Date
Bao Chuong	7/29/19
Approved by:	Date

- a. Were you aware of the HQ directive to Region 5 to no longer work with ATSDR or seek their assistance? If so, who in HQ issued the directive?

(b) (5), (b) (6)

- b. What are your thoughts on the directive to no longer work with ATSDR or seek their assistance?

During the November 2018 public meeting, EPA publicly announced that a risk assessment based on monitoring data being collected would be conducted. (b) (5)

[Evaluator note: (b) (5)]

#### Directive Not to Conduct Inspections at Ethylene Oxide Facilities

12. We were told that OAR HQ issued a directive not to conduct inspections at ethylene oxide facilities unless a state invites the region to conduct a joint inspection.

- a. Were you aware of the HQ directive to not conduct inspections at ethylene oxide facilities unless a state invites the region to conduct a joint inspection? If so, who in HQ issued the directive?

(b) (5), (b) (6)

- b. Was the HQ directive directed towards all regions?

Did not ask. See response to 12a.

#### Directive Not to Send 114 Letters to Ethylene Oxide Facilities

13. According to Region 5 staff and managers, Sterigenics and Ele had been uncooperative when the region requested information. Region 5 staff and managers wanted to send 114 letters to Sterigenics and Ele, but OAR HQ told them not to.

- a. Were you aware of the HQ directive not to send 114 letters to ethylene oxide facilities?

(b) (5), (b) (6)

- b. If so, who in HQ issued the directive?

Prepared by:	Date
Bao Chuong	7/29/19
Approved by:	Date



Did not ask. See response to 13a.

- c. Was the HQ directive directed towards all regions?

Did not ask. See response to 13a.

- d. We understand that on December 18, 2015, Region 6 sent a 114 letter to Denka to obtain information necessary to determine compliance with the Clean Air Act, the emissions inventory requirements of the Louisiana SIP, and the facility permit. Since the December 18, 2015 114 letter to Denka, has anyone from Region 6 wanted to send another 114 letter to Denka? If so, was the 114 letter sent? If not, why not?

(b) (5)

- e. Have there been any cases in which Region 6 had to get permission from HQ or OAQPS to send a 114 letter?

(b) (5)

[Evaluator note: (b) (6) provided us a copy of the 11/21/18 memo (Source B) that superseded the (b) (6) memo.]

- f. Has Region 6 sent a 114 letter to any ethylene oxide facilities in the region? If not, why not?

(b) (5), (b) (6).

- g. Does Region 6 plan to inspect any ethylene oxide facilities in the region? If not, why not?

(b) (5), (b) (6).

#### Directive Not to Conduct Monitoring at Ethylene Oxide Facilities

14. We have heard that OAR HQ does not want any regions to conduct ambient monitoring at ethylene oxide facilities other than what was done at Sterigenics in Willowbrook.

- a. Are you aware of the HQ directive not to conduct monitoring at ethylene oxide facilities? If so, who in HQ issued the directive?

Prepared by:	Date
Bao Chuong	7/29/19
Approved by:	Date

(b) (5), (b) (6)

#### Directive Not to Do Modeling of Ethylene Oxide Facilities

15. We have heard that the region must get permission from OAQPS before starting any modeling of ethylene oxide facilities.

- a. Are you aware of the HQ directive to seek permission from OAQPS before starting any modeling of ethylene oxide facilities? If so, who in HQ issued the directive?

(b) (5), (b) (6)

Reviewer Comment (and Date of Review)	Team Response (and Date of Response)	Resolution (and Date of Resolution)
No comments.		WP approved. RML 8/1/19

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	7/29/19
<b>Approved by:</b>	<b>Date</b>

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.02.ai**

**PURPOSE:** Obtain information regarding Region 6's role in addressing ethylene oxide and chloroprene emissions from stationary sources.

**SCOPE:** This workpaper summarizes an interview with (b) (6), of EPA Region 6, to obtain information about (b) (6) knowledge of how EPA Region 6 works to address ethylene oxide and chloroprene emissions.

**SOURCE:** See the list of meeting participants below.

**DATE and TIME:** 7/18/19, 9:00am – 10:00am CDT.

**LOCATION:** Region 6 Office in Dallas, TX, Conference Room (b) (6)

**PARTICIPANTS:**

**Region 6**

(b) (6)

**OIG – Office of Audit and Evaluation – Air Directorate**

Renee McGhee-Lenart, Project Manager, (913) 551-7534

Bao Chuong, Physical Scientist, (415) 947-4533

Andrew Lavenburg, Social Scientist, (919) 541-1871 (participated in meeting via telephone)

**CONCLUSION:** No conclusions drawn from this one meeting.

**DETAILS:**

Prior to the interview, Ms. McGhee-Lenart provided some background on the OIG audit, explained the audit objective and also provided the key questions that members of Congress had ask OIG to evaluate.

Questions asked by OIG during the interview are in black font, below, with a summary of the discussion in response to each question provided in blue font.

**Background on (b) (6)**

1. What is your title or role?

(b) (6)

2. How long have you been in your current position?

(b) (6)

3. Who do you report to?

(b) (6)

**HQ Directives**

4. Do you have knowledge of the following HQ directives or heard of the following HQ directives?

- Directive not to conduct inspections at ethylene oxide facilities.

(b) (5), (b) (6)

- Directive not to conduct monitoring at ethylene oxide facilities.

(b) (5), (b) (6)

- Directive not to do modeling at ethylene oxide facilities.

(b) (5), (b) (6)

- Directive not to send 114 letters to ethylene oxide facilities.

(b) (5), (b) (6)

**Section 114 Letter to Denka**

5. We understand that on December 18, 2015, EPA sent a 114 letter to Denka to obtain information necessary to determine compliance with the Clean Air Act, the emissions inventory requirements of the Louisiana SIP, and the facility permit. Subsequently,

NEIC, along with 3 Region 6 air inspectors and an LDEQ inspector, conducted an onsite inspection of Denka from June 6 – 10, 2016.

- a. Similarly, has Region 6 sent a 114 letter to any ethylene oxide facilities in the region? If not, why not?

(b) (5), (b) (6)

Ms. McGhee-Lenart asked if the letters that Louisiana sent to its facilities were available to the public. (b) (6) said that the letters are publicly available and can be found in and LDEQ database online- Electronic Document Management System (EDMS). **Evaluator Note- EDMS can be found at:**  
<https://www.deq.louisiana.gov/page/edms>

- b. Similarly, does Region 6 plan to inspect any of the ethylene oxide facilities in the region? If not, why not?

(b) (5), (b) (6)

#### **Onsite Visit of Denka May 18, 2016**

6. We understand that OAQPS conducted a site visit of Denka on May 18, 2016 to gather information on the processes and air pollution controls at the facility.
  - a. Did you participate in the site visit? If so, please provide a high-level overview of what was found.

(b) (6)

- b. Do you know whether any of the information found will be used in a potential new risk and technology review?

Question not asked due to response to 6.a

#### Current NESHAP for Group I Polymers and Resins

7. Please provide a high-level overview of the NESHAP for Group I polymers and resins, specifically as they apply to neoprene production facilities, such as Denka.

(b) (6), (b) (5)



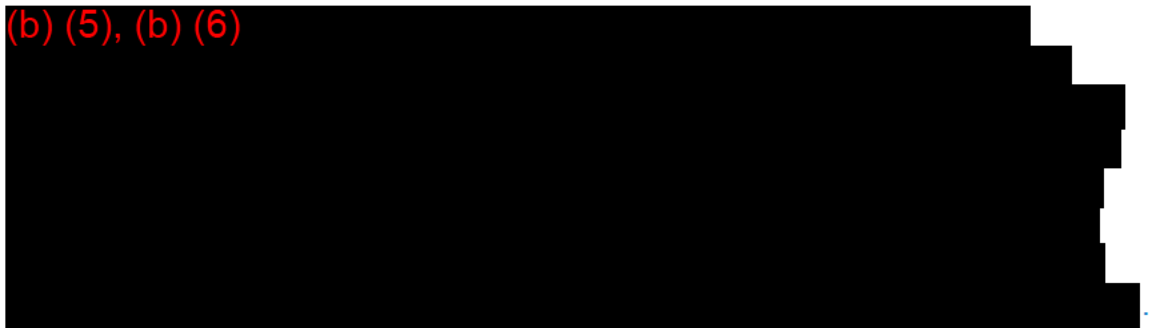
8. Do you think the current NESHAP for Group 1 polymers and resins is protective of human health? If not, what existing standards need to be revised or what new standards need to be implemented?

(b) (6) said that (b) (6) is not a toxicologist, and has no experience in risk assessment, so (b) (6) said that (b) (6) was not comfortable addressing this question.

#### Onsite Inspection of Denka June 6-10, 2016


9. We understand that EPA's NEIC conducted an onsite inspection of Denka from June 6 to June 10, 2016, and that (b) (6) Region 6 air inspectors ((b) (6)) and one LDEQ inspector participated in the inspection. Did you assist with the inspection or did you just observe the inspection?

(b) (5), (b) (6)




10. Please provide a high-level overview of the inspection findings.

(b) (5), (b) (6)

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11. Did the inspection result in any enforcement actions taken against Denka? If so, please elaborate.

(b) (5), (b) (6)

A large rectangular area of text is completely redacted with black ink.

12. Has NEIC, Region 6, or LDEQ conducted another inspection to verify that violations have been corrected? If so, when did the inspection take place and has Denka corrected all violations?

(b) (5), (b) (6)

A large rectangular area of text is completely redacted with black ink.

13. If Denka has corrected all violations, has ambient concentrations of chloroprene decreased to the point that it's not resulting in a 100-in-1 million cancer risk?

This question was not asked due to response provided in Question 12.

14. Have there been times since January 2017 when you or someone else in Region 6 wanted to conduct an onsite inspection at Denka or other facilities but was told not to? If so, please elaborate.

(b) (5), (b) (6)

A single line of text is redacted with black ink.

15. Have there been times since January 2017 when you or someone else in Region 6 wanted to send a 114 letter to Denka or other facilities but was told not to? If so, please elaborate.

(b) (5), (b) (6)

16. Have there been times since January 2017 when you or someone else in Region 6 wanted to take an enforcement action against Denka or other facilities but was told not to? If so, please elaborate.

(b) (6), (b) (5)

(b) (5), (b) (6)

(b) (5), (b) (6)

17. Have there been times since January 2017 when you or someone else in Region 6 wanted Denka to conduct its own monitoring, such as monitoring for fugitive emissions? Please elaborate.

(b) (5), (b) (6)

#### **State Inspections**

18. Has LDEQ conducted onsite inspections of Denka since June 2016?

(b) (5), (b) (6)



- a. If so, when were the state inspections?

Question not asked due to response for Question 18.

- b. Did you or anyone else from Region 6 participate in the inspections?

Question not asked due to response for Question 18.

- c. Did LDEQ take any enforcement actions? If so, please elaborate.

Question not asked due to response for Question 18.

(b) (5)

19. We understand (b) (5)

(b) (5), (b) (6)

Ms. McGhee-Lenart asked about staffing (b) (5), (b) (6)

Preparer's Initials and Date	
AJL	7/29/19

Reviewer Comment (and Date of Review)	Team Response (and Date of Response)	Resolution (and Date of Resolution)
No comments.		WP approved.
RML 8/14/19		RML 8/14/19

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.02.aj**

**PURPOSE:** Obtain information regarding Region 6's role in addressing ethylene oxide and chloroprene emissions from stationary sources.

**SCOPE:** This workpaper summarizes an interview with (b) (6), of EPA Region 6, to obtain information about (b) (6) knowledge of how EPA Region 6 works to address ethylene oxide and chloroprene emissions.

**SOURCE:** See the list of meeting participants below.

**DATE and TIME:** 7/18/19, 3:00pm – 4:00pm CDT.

**LOCATION:** Region 6 Office in Dallas, TX, Conference Room (b) (6)

**PARTICIPANTS:**

**Link:** WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docxRegion 6 (b) (6)

**OIG – Office of Audit and Evaluation – Air Directorate**

Renee McGhee-Lenart, Project Manager, (913) 551-7534

Bao Chuong, Physical Scientist, (415) 947-4533

Andrew Lavenburg, Social Scientist, (919) 541-1871 (participated in meeting via telephone)

**CONCLUSION:** No conclusions drawn from this one meeting.

**DETAILS:**

Prior to the interview, Ms. McGhee-Lenart provided some background on the OIG audit, explained the audit objective and also provided the key questions that members of Congress had ask OIG to evaluate.

Questions asked by OIG during the interview are in black font, below, with a summary of the discussion in response to each question provided in blue font.

**Background on (b) (6)**

1. What is your title or role?

(b) (6)

Preparer's Initials and Date	
AJL	8/19/19
RML	8/20/19

(b) (6)

2. How long have you been in your current position?

(b) (6)

3. Who do you report to?

(b) (6)

#### HQ Directives

4. Do you have knowledge of the following HQ directives or heard of the following HQ directives?

- Directive not to conduct inspections at ethylene oxide facilities.

(b) (5), (b) (6)

- Directive not to conduct monitoring at ethylene oxide facilities.

Preparer's Initials and Date	
AJL	8/19/19
RML	8/20/19

(b) (5), (b) (6)

- Directive not to do modeling at ethylene oxide facilities.

(b) (5), (b) (6)

- Directive not to send 114 letters to ethylene oxide facilities.

(b) (5), (b) (6)

### Communicating Health Risks to the Public

5. Does EPA have to follow any EPA regulations, policies, procedures, or protocols that would require the agency to communicate health risks from air toxics emissions, such as chloroprene and ethylene oxide emissions, to the public?

(b) (6) said that (b) (6) is not aware of any statutes or requirements. (b) (6) that (b) (6) is aware that risk communication has been discussed in Region 6, but (b) (6) is not aware of any written policy regarding communicating health risks. (b) (5), (b) (6)

6. With regards to the release of the 2014 NATA to the public on August 22, 2018,
  - a. Did you participate in any conference calls or meetings with HQ or OAQPS regarding the roll out?

(b) (5), (b) (6)

- b. If so, what were the expectations of the regions regarding the rollout of the 2014 NATA?


(b) (5), (b) (6)

Mr. Chuong asked if there were any expectations to talk to communities regarding risk. (b) (6) said that (b) (5)


Mr. Chuong asked if there were any expectations for public affairs to inform the public about the 2014 NATA results ahead of the public release and be ready for questions from the public about the NATA results. He asked if (b) (6) told public affairs people in the Regions to do anything specific.

Preparer's Initials and Date	
AJL	8/19/19
RML	8/20/19

(b) (5), (b) (6)




Ms. McGhee-Lenart asked if Region 6 was communicating to communities about potential elevated risks that were identified prior to the NATA release.




c. We understand that OAQPS had listed 10 ethylene oxide facilities in Region 6 as contributing to elevated cancer risks.

i. What stakeholders are you expected to reach out to?

(b) (6), (b) (5)



(b) (6), (b) (5)



ii. Have you reached out to all these stakeholders? If not, why not?


Question not asked due to response to 6.c.i

iii. What do you communicate to these stakeholders regarding the 10 high-risk ethylene oxide facilities?

Question not asked due to response to 6.c.i


d. Did you develop a communications plan for each of the 10 high-risk ethylene oxide facilities? If so, did you have to get these communication plans approved by HQ or OAQPS?

(b) (5), (b) (6)



(NOTE- please see w/p J.06 [Link](#)., Source B for a copy of the draft Region 6 communication plan).

(b) (5)



#### Region 6 Actions Taken On the 10 High-Risk Ethylene Oxide Facilities

7. What actions has Region 6 taken on the 10 high-risk ethylene oxide facilities?

Preparer's Initials and Date	
AJL	8/19/19
RML	8/20/19

(b) (5), (b) (6)

8. Have you communicated about these Region 6 actions to communities, elected officials, advocacy groups, and other stakeholders? What have been the stakeholders' reactions to Region 6's actions so far?

(b) (5), (b) (6)

9. We understand that the 2014 NATA shows census tracts around Denka having total cancer risks attributed to both chloroprene and ethylene oxide emissions. Have you communicated to the community surrounding Denka about the even higher potential cancer risks they may be experiencing due to the recently released IRIS risk value for ethylene oxide? If so, what were their reactions?

(b) (5), (b) (6)

#### Ethylene Oxide Coordination Calls

10. We understand that OAQPS leads the biweekly ethylene oxide coordination calls. Have you participated in these calls? If so, what was discussed in these calls?

(b) (5), (b) (6) (b) (5), (b) (6)

Ms. McGhee-Lenart asked about what is discussed on occasions when communication topics are brought up on the calls (b) (5), (b) (6)

Preparer's Initials and Date	
AJL	8/19/19
RML	8/20/19

[Link: WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docx](#)Ms.  
McGhee-Lenart asked if OAQPS provides any milestones on the calls for when Regions should be getting certain stuff done. (b) (5), (b) (6)

Reviewer Comment (and Date of Review)	Team Response (and Date of Response)	Resolution (and Date of Resolution)
No comments.		WP approved. RML 8/20/19



**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.02.ak**

**PURPOSE:** To interview (b) (6) regarding EPA's role in addressing ethylene oxide and chloroprene emissions.

**SCOPE:** Interviewed (b) (6) regarding EPA's role in addressing ethylene oxide and chloroprene emissions.

**SOURCE:** A) See list of participants below.

**DATE and TIME:** 7/19/19, 9:00 – 10:30 AM CDT.

**LOCATION:** (b) (6) Conference Room on (b) (6) Dallas, TX

**PARTICIPANTS:**

(b) (6)

OIG – Office of Audit and Evaluation – Air Directorate  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy points from the interview included:

- (b) (5), (b) (6)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	7/29/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	8/01/2019

- (b) (5)

- (b) (5)

**DETAILS:**

After introductions, Renee provided background information on our assignment. She explained that initially, we sent out a notification memo with an objective to determine whether EPA's residual risk and technology review process has sufficiently identified and addressed any elevated cancer risks from air toxics emitted by facilities. We then received four Congressional requests related to ethylene oxide. Our management decided to have us address the four Congressional requests. We have decided that we will write a report to address the four Congressional requests.

As a result of the four Congressional requests, we have expanded the scope to address the following Congressional questions:

- Whether EPA senior political appointees instructed EPA inspectors to avoid conducting inspections at EtO emitting facilities across EPA Regions 5 and 6.
- Have inspections by the EPA been conducted on [ethylene oxide-emitting] facilities in Regions 5 and 6? If not, why?
- Whether the EPA complied with all statutory, regulatory and policy requirements and protocols in disclosing public health information about ethylene oxide air emissions from the Sterigenics facility in DuPage County, Illinois, the Medline Industries, Inc. facility in Lake County, Illinois and the Vantage Specialty Chemicals, Inc. facility in Lake County, Illinois.

After providing the background, Renee then proceeded to ask the following questions. (b) (6)'s response is in blue text.

Background on (b) (6)

1. What is your title or role?

(b) (6)

2. How long have you been in your current position?

(b) (6)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	7/29/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	8/01/2019

3. Who do you report to?

(b) (6)

#### HQ Directives

4. Do you have knowledge of the following HQ directives or heard of the following HQ directives?

- Directive not to conduct inspections at ethylene oxide facilities. (b) (5)
- Directive not to conduct monitoring at ethylene oxide facilities. (b) (5), (b) (6)
- Directive not to do modeling at ethylene oxide facilities. (b) (5), (b) (6)
- Directive not to send 114 letters to ethylene oxide facilities. (b) (5), (b) (6)

#### Ethylene Oxide

5. Please describe what your division is working on in regards to ethylene oxide facilities in Region 6?

When the 2014 NATA first came out back in 2018 and showed excess cancer risks, we did what we had done in the past with previous National Air Toxics Assessment (NATA) rollouts. The Office of Air Quality Planning and Standards (OAQPS) provided us with a list of high-risk facilities. We met with our states to go over the list. We gave states a heads up before the rollout that they may be faced with an onslaught of questions. (b) (5)

(b) (5)

#### Section 114 Letter to Denka

6. We understand that on December 18, 2015, Region 6 sent a 114 letter to Denka to obtain information necessary to determine compliance with the Clean Air Act, the emissions inventory requirements of the Louisiana SIP, and the facility permit. Subsequently, NEIC, along with 3 Region 6 air inspectors and an LDEQ inspector, conducted an onsite inspection of Denka from June 6 – 10, 2016.
- a. What was the impetus for assessing compliance at Denka? Was it due to the 2011 NATA showing elevated cancer risks attributed to chloroprene emissions from Denka?

Prepared by:	Date
Bao Chuong	7/29/19
Approved by:	Date
Renee McGhee-Lenart	8/01/2019

(b) (5)

When the new IRIS risk value for ethylene oxide was issued in 2016, the regions were alerted of that. (b) (5)

(b) (5)

(b) (5)

The Texas Commission on Environmental Quality (TCEQ) is the second largest government environmental organization after EPA in terms of number of employees.

- b. Similarly, has Region 6 sent a 114 letter to any ethylene oxide facilities in the region? If not, why not?

(b) (5)

(b) (5)

Link: A (b) (5)

(b) (5), (b) (6)

(b) (5)

Prepared by:	Date
Bao Chuong	7/29/19
Approved by:	Date
Renee McGhee-Lenart	8/01/2019

(b) (5)

(b) (5)

(b) (5)

- c. Similarly, does Region 6 plan to inspect any of the ethylene oxide facilities in the region?  
If not, why not?

(b) (5)

- d. Does Region 6 have a policy to assess compliance when NATA results show a facility  
contributing to elevated cancer risk?

(b) (5)

#### Onsite Visit of Denka May 18, 2016

7. We understand that OAQPS conducted a site visit of Denka on May 28, 2016 to gather  
information on the processes and air pollution controls at the facility.

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	7/29/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	8/01/2019

- a. Did anyone from Region 6 participate in the site visit?

(b) (5), (b) (6)

- b. Do you know whether any of the information found will be used in a potential new risk and technology review?

Did not ask. See response to 7a.

#### Current NESHAP for Group I Polymers and Resins

8. Do you think the current NESHAP for Group 1 polymers and resins is protective of human health? If not, what existing standards need to be revised or what new standards need to be implemented?

I don't know. I am not a toxicologist. (b) (5)

#### Onsite Inspection of Denka June 6-10, 2016

9. We understand that EPA's NEIC conducted an onsite inspection of Denka from June 6 to June 10, 2016, and that three Region 6 air inspectors and one LDEQ inspector participated in the inspection.

- a. Were you briefed on the inspection findings?

(b) (5)

- b. Were you involved with reviewing the inspection report?

(b) (5)

10. Did the inspection result in any enforcement actions taken against Denka? If so, please elaborate.

(b) (5), (b) (6)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	7/29/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	8/01/2019

(b) (5)

[Link: A](#) (b) (5)

11. Has NEIC, Region 6, or LDEQ conducted another inspection to verify that violations have been corrected? If so, when did the inspection take place and has Denka corrected all violations?

Did not ask. See answer to Question 10.

12. If Denka has corrected all violations, has ambient concentrations of chloroprene decreased to the point that it's not resulting in a 100-in-1 million cancer risk?

Did not ask. See answer to Question 10.

13. Have there been times since January 2017 when Region 6 wanted to conduct an onsite inspection at Denka or other facilities but was told not to? If so, please elaborate.

(b) (5), (b) (6)

14. Have there been times since January 2017 when Region 6 wanted to send a 114 letter to Denka or other facilities but was told not to? If so, please elaborate.

(b) (5), (b) (6)

15. Have there been times since January 2017 when Region 6 wanted to take an enforcement action against Denka or other facilities but was told not to? If so, please elaborate.

(b) (5), (b) (6)

16. Have there been times since January 2007 when Region 6 wanted Denka or other facilities to conduct its own monitoring, such as monitoring for fugitive emissions? Please elaborate.

(b) (5), (b) (6)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	7/29/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	8/01/2019

## State Inspections

17. Has LDEQ conducted onsite inspections of Denka since June 2016?

(b) (5), (b) (6)

a. If so, when were the state inspections?

Did not ask. See response to 17.

b. Did Region 6 participate in the inspections?

Did not ask. See response to 17.

c. Did LDEQ take any enforcement actions? If so, please elaborate.

Did not ask. See response to 17.

18. Are Region 6 states conducting inspections at ethylene oxide facilities in a timely manner using the agreed upon dates in their approved state compliance monitoring plan? How does Region 6 determine that the states are conducting these inspections in a timely manner?

(b) (5), (b) (6)

We also review state inspection efforts under the State Review Framework. There is also a grants component. If there is a grant commitment, then states have to meet those commitments.

(b) (5)

19. We understand that (b) (5)

?

(b) (5), (b) (6)

## IRIS Assessments

20. Prior to the development of the 2011 NATA by OAQPS, were you aware that the IRIS program issued a new IRIS assessment for chloroprene in September 2010?

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	7/29/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	8/01/2019



(b) (5)

21. Prior to the development of the 2014 NATA by OAQPS, were you aware that the IRIS program issued a new IRIS assessment for ethylene oxide in December 2016?

(b) (5)

I should point out that NAAQS does not take into account air toxics. (b) (5)

(b) (5)

Reviewer Comment (and Date of Review)	Team Response (and Date of Response)	Resolution (and Date of Resolution)
No comments.		WP approved. RML 8/1/19

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	7/29/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	8/01/2019

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.02.b**

**PURPOSE:** To interview (b) (6) regarding Region 5's role in addressing ethylene oxide emissions.

**SCOPE:** Interviewed (b) (6) regarding Region 5's role in addressing ethylene oxide emissions.

**SOURCE:** A) Email from (b) (6) about (b) (5)

B) See the list of meeting participants below.

**DATE and TIME:** 4/1/19, 12:30 – 2:00 PM CDT.

**LOCATION:** Region 5 Office in Chicago, (b) (6).

**PARTICIPANTS:**

[Link: WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docx](#)Region 5

(b)(6)

OIG – Office of Audit and Evaluation – Air Directorate  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy points from the interview included:

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	4/8/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/30/19

- (b) (5) [REDACTED]
- (b) (5) [REDACTED]
- (b) (5) [REDACTED]

#### DETAILS:

#### **BACKGROUND**

After introductions, we discussed the following topics and asked questions relating to those topics.

Background on (b)(6)


(b) (6) [REDACTED]

#### **Region 5 Efforts to Address Ethylene Oxide Emissions Initially**


According to (b)(6), OAQPS released Version 1 of the 2014 NATA to the regions beginning of 2017, not long after the new IRIS assessment of ethylene oxide was completed. In June 2017, a workgroup consisting of OAQPS and regional representatives was formed to address ethylene oxide risk. (b) (6), (b) (5) [REDACTED]

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	4/8/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/30/19

(b) (5)

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**A** [Link:](#) (b)(6) stated that (b) (5)

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(b) (5)

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**B** [Link:](#) [Link:](#) (b) (5)

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(b) (5)

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Ambient Monitoring of Sterigenics in May 2018

Prepared by:	Date
Bao Chuong	4/8/19
Approved by:	Date
Renee McGhee-Lenart	4/30/19

(b) (5), (b) (6)

(b) (5)

EPA conducted ambient monitoring around Sterigenics in May 2018 with assistance from OAQPS. QA/QC monitoring results came back in June 2018. (b) (5), (b) (6)

ARD provided monitoring results to ATSDR so that they can work on the letter health consultation on ethylene oxide emissions from Sterigenics.

RA Cathy Stepp eventually learned of the monitoring results. She told staff to release the monitoring results to the public, issue a press release, and inform the Willowbrook mayor. This was all put on hold as HQ did not permit the release of the results to the public. The information was eventually released when ATSDR released the letter health consultation in August 2018. Prior to the August 2018 release of the letter health consultation, ATSDR sent a draft of it to ARD Director Ed Nam in July 2018.

(b) (5)

**C** [Link](#); [Link](#); [Link](#); [Link](#); HQ / OAQPS Directives

(b) (5)

Prepared by:	Date
Bao Chuong	4/8/19
Approved by:	Date
Renee McGhee-Lenart	4/30/19

(b) (5)

(b) (5)

[Link:](#) WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach, (b) (6) heard that the agency was pursuing a two-prong strategy to address ethylene oxide emissions. One prong is through regulations, such as conducting risk and technology reviews (RTRs) and revising the National Emission Standards for Hazardous Air Pollutants (NESHAP). The other prong is to address facilities that show up as contributing to high cancer risks in NATA by sharing modeling results with facilities, obtaining accurate emissions data and modeling parameters from the facilities, conducting ambient monitoring, and pursuing voluntary actions.

(b) (5), (b) (6)

#### Region 5 Efforts to Address Ethylene Oxide Emissions from Hospitals

(b) (5)

(b) (5)

(b) (5)

#### Inspections

Prepared by:	Date
Bao Chuong	4/8/19
Approved by:	Date
Renee McGhee-Lenart	4/30/19

(b) (5)

D [Link:](#) [Link:](#) (b) (5)

(b) (5)

Expectations of States When Draft 2014 NATA Released to Them

(b) (5)

Medline and Vantage


(b) (5)

(b) (6)

(Source A is the email from

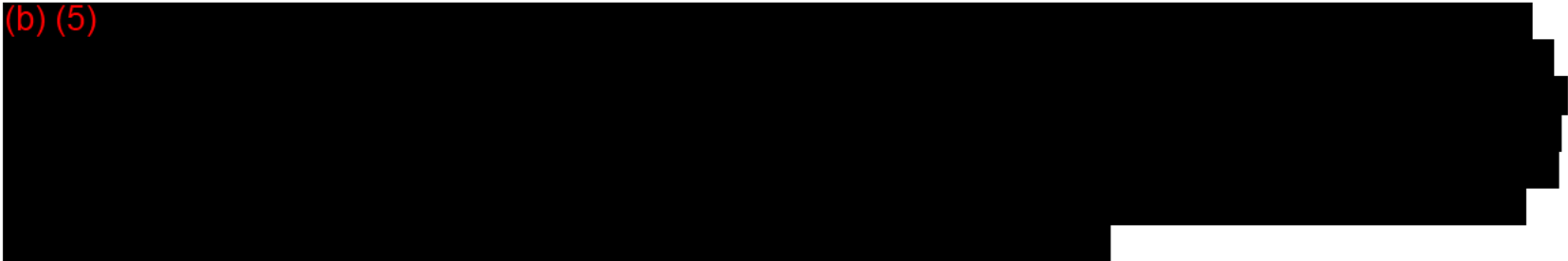
Prepared by:	Date
Bao Chuong	4/8/19
Approved by:	Date
Renee McGhee-Lenart	4/30/19

(b) (5), (b) (6)



More on Sterigenics

(b) (5)



Community Engagement

(b) (5)



Prepared by:	Date
Bao Chuong	4/8/19
Approved by:	Date
Renee McGhee-Lenart	4/30/19



(b) (5)

#### Status of Facilities

(b) (5)

#### Whether Preliminary 2014 NATA Data Should Have Been Released in December 2017

(b) (5)

Prepared by:	Date
Bao Chuong	4/8/19
Approved by:	Date
Renee McGhee-Lenart	4/30/19

Whether NATA Block-Level Data Should Be Released to the Public

(b) (5)

Risk Communication

(b) (5)

Whether EPA Should Have Released the Monitoring Data in June 2018 Instead of August 2018

(b) (5)

Reviewer Comment (and Date of Review)	Team Response (and Date of Response)	Resolution (and Date of Resolution)
No comments. RML 4/30/19		WP approved. RML 4/30/19

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	4/8/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/30/19

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.02.c**

**PURPOSE:** To interview (b)(6) regarding Region 5's role in addressing ethylene oxide emissions.

**SCOPE:** Interviewed (b)(6) regarding Region 5's role in addressing ethylene oxide emissions.

**SOURCE:** A) See the list of meeting participants below.

**DATE and TIME:** 4/1/19, 2:30 – 3:30 PM CDT.

**LOCATION:** Region 5 Office in Chicago, (b) (6).

**PARTICIPANTS:**

Region 5

(b)(6)

**OIG – Office of Audit and Evaluation – Air Directorate**  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy points from the interview included:

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	4/8/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/30/19

- (b) (5)
- Region 5 created a webpage on Sterigenics, containing the May 2018 ambient monitoring data and a link to ATSDR's letter health consultation on ethylene oxide emissions from Sterigenics. This webpage was live for two hours in August 2018 before Region 5 was ordered by HQ to take it down.
- (b) (5)
- (b) (5)

#### DETAILS:

After introductions, we discussed the following topics and asked questions relating to those topics.

Background on (b)(6)

(b) (6)

#### Initial Region 5 Efforts to Address Ethylene Oxide Emissions

Link: (b) (6) explained that OAQPS provided a draft 2014 NATA to the regions and states for review. A list of facilities contributing to high cancer risks were provided to the regions. (b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	4/8/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/30/19

(b) (5) [Redacted]

(b) (5) [Redacted]

[Redacted]

D [Link](#): [Link](#): [Link](#): (b) (5), (b) (6) [Redacted]

[Redacted]

[Redacted]

Prepared by:	Date
Bao Chuong	4/8/19
Approved by:	Date
Renee McGhee-Lenart	4/30/19

## Ambient Monitoring of Ethylene Oxide Emissions Around Sterigenics

A [Link:](#) (b) (6), (b) (5)

[Redacted text block]

C [Link:](#) [Link:](#) (b) (5)

[Redacted text block]

E [Link:](#) (b) (6), (b) (5)

[Redacted text block]

Whether the May 2018 Ambient Monitoring Data Should Have Been Released to the Public in June 2018

Prepared by:	Date
Bao Chuong	4/8/19
Approved by:	Date
Renee McGhee-Lenart	4/30/19

(b) (5), (b) (6)

#### Communicating the May 2018 Ambient Monitoring Results to the Public

(b) (6) Region 5 had a webpage containing the May 2018 ambient monitoring results and a link to ATSDR's letter health consultation on ethylene oxide emissions from Sterigenics. The August 2018 webpage was up for two hours before it was ordered to be pulled down by HQ.

(b) (5), (b) (6)


HQ has taken over the lead when it comes to communicating with the public about ethylene oxide. HQ created the [eto@epa.gov](mailto:eto@epa.gov) email where the public can submit questions or inquiries to the agency. Region 5 has not had much interaction with the community since then.

#### Expectations of Regions and States When Draft 2014 NATA Released in January 2017

(b) (5)


Prepared by:	Date
Bao Chuong	4/8/19
Approved by:	Date
Renee McGhee-Lenart	4/30/19

(b) (5)

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Other Facilities in Region 5

(b) (5)

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**F** [Link:](#) (b) (5)

A rectangular area of the document is completely redacted with a solid black fill.

Prepared by:	Date
Bao Chuong	4/8/19
Approved by:	Date
Renee McGhee-Lenart	4/30/19



(b) (5)

Whether 2014 NATA Block-Level Data Should Be Released to the Public

(b) (5)

Reviewer Comment (and Date of Review)	Team Response (and Date of Response)	Resolution (and Date of Resolution)
		WP approved. RML 4/30/19

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	4/8/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/30/19

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.02.d**

**PURPOSE:** To interview (b)(6) regarding Region 5's role in addressing ethylene oxide emissions.

**SCOPE:** Interviewed (b)(6) regarding Region 5's role in addressing ethylene oxide emissions.

**SOURCE:** A) Region 5 ethylene oxide timeline. (b) (6)

B) 6/20/18 – 6/21/18 emails showing (b) (5)  
(b) (6) (b) (6)

C) 6/21/18 OAQPS PowerPoint briefing. (b) (6)

D) 6/21/18 – 6/22/18 emails showing (b) (5)  
(b) (6)

E) 6/22/18 email showing (b) (5), (b) (6) (b) (6)

F) June – July 2018 (b) (5) (b) (6)

G) 7/23/18 ARD meeting with ORA with briefing documents. (b) (6)

H) OAR Meeting Request for (b) (6) for 7/26/18 meeting. (b) (6)

I) Outlook invitation for the 7/26/18 meeting. (b) (6)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	5/16/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	5/16/19

J) Summary of the 2014 NATA results on a national level. (b) (6)

K) Summary of the 2014 NATA results by region showing facilities contributing to high cancer risks. (b) (6)

L) Outlook meeting invitations for conference calls between Region 5, ATSDR, and OAQPS regarding ethylene oxide next steps. (b) (6)

M) Region 5 making suggestions to OAQPS regarding (b) (5). (b) (6)

N) Documents relating to the 8/22/18 release of the 2014 NATA. (b) (6)

O) Follow-up to Source N. (b) (6)

P) 8/22/18 email regarding upcoming webinar on the 2014 NATA for tribes and another webinar for advocacy groups, state/local agencies, and federal agencies (b) (6)

Q) 8/22/18 emails relating to (b) (5)

(b) (6)

Q2) (b) (6) emailed (b) (6) a screenshot of the Sterigenics webpage before it was pulled down. (b) (6)

R) Emails relating to (b) (5). (b) (6)

S) 9/25/18 email from (b) (5), (b) (6)

(b) (6)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	5/16/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	5/16/19

T) 9/28/18 email from (b) (5), (b) (6) . (b) (6)

U) Emails showing Region 5 being invited by Michigan and Cook County to (b) (5) . (b) (6)

V) Emails showing (b) (5)

(b) (6)

W) Email relaying (b) (5), (b) (6) . (b) (6)

X) Status of (b) (5) (b) (6)

Y) (b) (5) . (b) (6)

Z) Status of Region 5 ethylene oxide-emitting facilities. (b) (6)

AA) See the list of meeting participants below.

**DATE and TIME:** 4/2/19, 10:30 AM – 12:00 PM CDT.

**LOCATION:** Region 5 Office in Chicago, (b) (6) .

**PARTICIPANTS:**

[Link:](#) WP E.08.a Region 5

(b)(6)

Prepared by:	Date
Bao Chuong	5/16/19
Approved by:	Date
Renee McGhee-Lenart	5/16/19

OIG – Office of Audit and Evaluation – Air Directorate  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy points from the interview included:

- (b) (6), (b) (5) [REDACTED]

**DETAILS:**

**BACKGROUND**

After introductions, we discussed the following topics and asked questions related to those topics.

Background on (b)(6) [REDACTED]

(b)(6) [REDACTED]

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	5/16/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	5/16/19

i. (b)(6)

(b)(6)

#### Early Efforts to Address Ethylene Oxide Emissions

**B** [Link](#): [Link](#): [Link](#): [Link](#): [Link](#): [Link](#): (b)(6) proceeded to provide a timeline of key events associated with Sterigenics and ethylene oxide in Region

5. (b) (6), (b) (5)

(b) (5), (b) (6)  
I (b) (5), (b) (6)

**C** [Link](#): [Link](#): (b) (5), (b) (6)

Prepared by:	Date
Bao Chuong	5/16/19
Approved by:	Date
Renee McGhee-Lenart	5/16/19

(b) (5)

(Source B > Pg. 1 of 4 > email with date/time stamp of 6/21/18, 8:43AM)

#### Ambient Monitoring of Ethylene Emissions from Sterigenics In May 2018

A [Link:](#) (b) (5), (b) (6)

Region 5 received preliminary monitoring results from ERG on May 30, 2018. There were phone calls with ERG to make sure Region 5 interpreted the monitoring results correctly. On June 6, the Air Toxics and Assessment Branch (ATAB) staff formally briefed the Air and Radiation Division (ARD) Director, Ed Nam, on the preliminary modeling results. On June 7, ATAB met with ARD's Air Enforcement and Compliance Assurance Branch (AECAB) regarding the preliminary modeling results. (b) (5)

On 6/15/18, ARD completed QA/QC of the monitoring data.

Region 5 Wanted to Release the May 2018 Ambient Monitoring Results to the Public but Was Told Not to by HQ

Prepared by:	Date
Bao Chuong	5/16/19
Approved by:	Date
Renee McGhee-Lenart	5/16/19

**D** [Link:](#) (b) (5)

(b) (6), (b) (5)

(b) (6), (b) (5)

Prepared by:	Date
Bao Chuong	5/16/19
Approved by:	Date
Renee McGhee-Lenart	5/16/19



(b) (5), (b) (6)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(b) (6), (b) (5)

Ele Facility

(b) (5)

[REDACTED]

Prepared by:	Date
Bao Chuong	5/16/19
Approved by:	Date
Renee McGhee-Lenart	5/16/19

- 1

\_\_\_\_\_

- 1

- (b) (5)
- (b) (5)

[Link:](#) WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docx On 7/26, (b) (6) had a meeting with RAs where (b) (6) announced the two-pronged approach/hybrid strategy to address ethylene oxide emissions. First prong is addressing ethylene oxide emissions through regulations, such as conducting RTRs and updating or revising NESHAPs or MACT standards. [Link:](#) WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach. (b) (5)

The second prong is to take a closer look at facilities that contribute to high cancer risks according to NATA by asking the facilities to verify emissions data and modeling parameters used in the 2014 NATA, redo modeling if received updated emissions data or modeling parameters, and pursue voluntary actions (e.g., adding pollution controls).

(b) (5), (b) (6)

\_\_\_\_\_

- (b) (5), (b) (6)

#### Coordination of Public Release of ATSDR Letter Health Consultation on Sterigenics and Public Release of 2014 NATA

On the same day, ATSDR issued the health consultation letter on Sterigenics to Ed Nam. Subsequent to that, there were conference calls between ATSDR, Region 5, and OAQPS regarding next steps. (b) (5), (b) (6)

[Evaluator note: (b) (6)] provided the Outlook meeting invitations for these conference calls. (Source L)]

#### Next Steps in Addressing Ethylene Oxide-Emitting Facilities

(b) (5)

[Evaluator note: (b) (6)] provided us with documents showing that these calls had taken place. Source M shows that:

Prepared by:	Date
Bao Chuong	5/16/19
Approved by:	Date
Renee McGhee-Lenart	5/16/19

- (b) (5), (b) (6)

## Public Release of the 2014 NATA

ATSDR released the Letter Health Consultation on Sterigenics on 8/21/18. EPA released the 2014 NATA on 8/22/18.

[Evaluator note: (b) (6) provided documents relating to the 8/22/18 release of the 2014 NATA. Source N shows that on 8/21/18, (b) (5)

Source N also shows the list of 25 ethylene oxide-emitting facilities that contribute to the high cancer risks (b) (5)

Source O was a follow-up to Source N with added fact sheets on the 2014 NATA and ethylene oxide.

(b) (5)

## Webpage on Ethylene Oxide Emissions from Sterigenics Pulled Down

**B Link:** On 8/22/18, the 2014 NATA webpage went live. The Region 5 Sterigenics webpage also went live at the same time, but it was short lived. About an hour later, HQ ordered Region 5 to pull the Sterigenics webpage down. (b) (5)

Prepared by:	Date
Bao Chuong	5/16/19
Approved by:	Date
Renee McGhee-Lenart	5/16/19

(b) (5)

The Sterigenics webpage eventually got back up on 10/2/18, but it was a little different from what was live on 8/22/18. Some of the health language had changed.

[Evaluator note: (b) (6)

Source Q contains:

- (b) (5)
- (b) (5)

#### Public Reactions to the 2014 NATA

Willowbrook Mayor Frank Trilla had seen the Sterigenics webpage before it was taken down and also downloaded a copy of the ATSDR letter health consultation on Sterigenics. (b) (5) Jim Payne, Jeff Kelley, Ed Nam, and Cathy Stepp were on the meeting panel that responded to questions from the public. At the meeting, Cathy committed to conducting more ambient monitoring. (b) (5)

(b) (5)

(b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	5/16/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	5/16/19

[Evaluator note: (b) (6)  
(see Source R)]

(b) (5)

[Evaluator note: (b) (6)]

I [REDACTED]  
I [REDACTED]

#### OAR and OAQPS Now the Contact Point on Ethylene Oxide and Sterigenics

In the 9/27/18 letter from (b) (5), (b) (6)

Also, on 9/28/18, (b) (5)

[Evaluator note: (b) (6)]

(Source T)]

#### Illinois Shut Down Sterigenics

Prepared by:	Date
Bao Chuong	5/16/19
Approved by:	Date
Renee McGhee-Lenart	5/16/19

(b) (5)

Other Ethylene Oxide-Emitting Facilities in Region 5

(b) (5)

(b) (5)

(b) (5)

[Evaluator note: (b) (6)]

(Source U)]

**F** [Link:](#) [Link:](#) (b) (5)

Evaluator note: (b) (5)

Prepared by:	Date
Bao Chuong	5/16/19
Approved by:	Date
Renee McGhee-Lenart	5/16/19

[Evaluator note: (b) (6), (b) (5) Source V)]

(b) (5)

(b) (5)

E Link: Link: (b) (5)

(b) (5)

[Evaluator note: (b) (6), (b) (5) provided us with a status of (b) (5) . (Source X)]

#### Final Thoughts

(b) (5)

Prepared by:	Date
Bao Chuong	5/16/19
Approved by:	Date
Renee McGhee-Lenart	5/16/19



(b) (5)

[Evaluator note: (b) (6)

(b) (5)

(Source Y) (b) (6)

[Source Z)]

(b) (5)

Reviewer Comment (and Date of Review)	Team Response (and Date of Response)	Resolution (and Date of Resolution)
No comments. RML 5/16/19		WP approved. RML 5/16/19

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	5/16/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	5/16/19

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.02.e**

**PURPOSE:** To interview (b)(6) regarding Region 5's role in addressing ethylene oxide emissions.

**SCOPE:** Interviewed (b)(6) regarding Region 5's role in addressing ethylene oxide emissions.

**SOURCE:** A) See the list of meeting participants below.

**DATE and TIME:** 4/2/19, 1:00 – 2:00 PM CDT.

**LOCATION:** Region 5 Office in Chicago, (b) (6).

**PARTICIPANTS:**

[Link:](#) WP E.08.a **D** [Link:](#) Region 5

(b)(6)

OIG – Office of Audit and Evaluation – Air Directorate  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy points from the interview included:

- (b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	5/14/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	5/16/19

- (b) (5) [REDACTED]
- (b) (5) [REDACTED]
- (b) (5) [REDACTED]
- (b) (5) [REDACTED]
- (b) (5) [REDACTED]
- (b) (5) [REDACTED]

**DETAILS:**

**BACKGROUND**

After introductions, we discussed the following topics and asked questions relating to those topics.

How (b)(6) Became Involved with Sterigenics and Ethylene Oxide Issues

(b) (5) [REDACTED]

(b) (5) [REDACTED]

(b) (5) [REDACTED]

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	5/14/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	5/16/19

## Sterigenics May 2018 Monitoring Results and Actions Taken

(b)(6) stated (b)(6) was with (b)(6) when they were briefed about the preliminary monitoring results. (b) (6), (b) (5)

[REDACTED]

(b) (6) ARD briefed the Office of the Regional Administrator (ORA) of the monitoring results. (b) (6)

(b) (5)

[REDACTED]

(b) (5)

[REDACTED]

(b) (6), (b) (5) . (b) (5)

[REDACTED]

## HQ Directive Not to Send CAA Section 114 Letters to Ethylene Oxide-Emitting Facilities

(b) (5)

[REDACTED]

(b) (5)

[REDACTED]

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	5/14/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	5/16/19

(b) (5)

#### Relationship Between Region 5 and HQ

(b) (5)

#### HQ Directive Not to Conduct Inspections at Ethylene Oxide-Emitting Facilities

**A** [Link:](#) [Link:](#) (b) (5)

OAQPS have started.] Evaluator's Note: Ethylene oxide coordination call between regions and

**E** [Link:](#) [Link:](#) According to (b) (6) (b) (5)


**B** [Link:](#) [Link:](#) Directive Not to Seek Assistance From ATSDR

(b) (5)

Prepared by:	Date
Bao Chuong	5/14/19
Approved by:	Date
Renee McGhee-Lenart	5/16/19


## Cooperative Federalism

(b) (5)

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Background on (b)(6)

(b)(6)

A horizontal rectangular area of the document is completely blacked out, indicating redacted content.

**C** [Link:](#) Impact of HQ's Actions on Ethylene Oxide Issues and Takeover of Region 5's Role

(b) (5)

A large rectangular area of the document is completely blacked out, indicating redacted content.A large rectangular area of the document is completely blacked out, indicating redacted content.

Prepared by:	Date
Bao Chuong	5/14/19
Approved by:	Date
Renee McGhee-Lenart	5/16/19

(b) (5)

#### List of 25 Facilities That Regions Should Focus On

(b) (5)

[Link:](#) WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docx (b) (5)

#### How Region 5 Views Itself

(b) (5)

Reviewer Comment (and Date of Review)	Team Response (and Date of Response)	Resolution (and Date of Resolution)
No comments. RML 5/16/19		Approved WP. RML 5/16/19

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	5/14/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	5/16/19

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<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	5/14/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	5/16/19



**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.02.f**

**PURPOSE:** To follow up with (b)(6) regarding Region 5's role in addressing ethylene oxide emissions.

**SCOPE:** Interviewed (b)(6) regarding Region 5's role in addressing ethylene oxide emissions.

**SOURCE:** A) Key dates in the development of the 2014 NATA (b) (6)

B) Regionally Applied Research Effort (RARE) proposal (b) (6)

C) RARE project communication plan (b) (6)

D) RARE project fact sheet (b) (6)

E) Forwarded 8/1/18 email from (b) (6) (b) (5)  
(b) (6)

F) Email about the 8/8/18 (b) (5) (b) (6)

G) List of 26 facilities in the Source F email. (b) (6)

H) Email from (b)(6) (b) (5)  
(b) (6)

I) Forwarded 7/30/18 email containing Source J (b) (6)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	5/15/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	5/16/19

J) (b) (5)  
(b) (6)

K) 8/13/18 (b) (5) Source J. (b) (6)

L) (b) (5) (b) (6)

M) See the list of meeting participants below.

**DATE and TIME:** 4/3/19, 9:00 – 10:00 AM CDT.

**LOCATION:** Region 5 Office in Chicago, (b) (6).

**PARTICIPANTS:**

Region 5

(b)(6)

OIG – Office of Audit and Evaluation – Air Directorate  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy points from the interview included:

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	5/15/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	5/16/19

- According to (b)(6), it has been EPA policy to notify elected officials, states, and advocacy groups two weeks ahead of the NATA release to the public. (b)(5)

- (b)(5)

- (b)(5)

- (b)(5)

- (b)(5)

#### DETAILS:

(b)(6) had spoken to us on (b)(6). (See WP H.02.c [Link](#); for details.) We had follow-up questions. Below are the topics discussed.

#### **Policy to Notify Mayors, States, and Advocacy Groups Head of Public Release of the 2014 NATA on 8/22/19**

(b)(6) the EPA policy is to notify mayors, states, and advocacy groups ahead of the public release of the National Air Toxics Assessment (NATA). The policy has been to notify them two weeks in advance of the public release of NATA. That is how it was with previous NATA rollouts. However, for the rollout of the 2014 NATA, that two-week advanced notice was cut down to one week because of the imminent release of the ATSDR letter health consultation on ethylene oxide emissions from Sterigenics.

#### **Medline**

(b)(5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	5/15/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	5/16/19

(b) (5)

Vantage

[Link: A](#) (b) (5)

Ele

(b) (5)

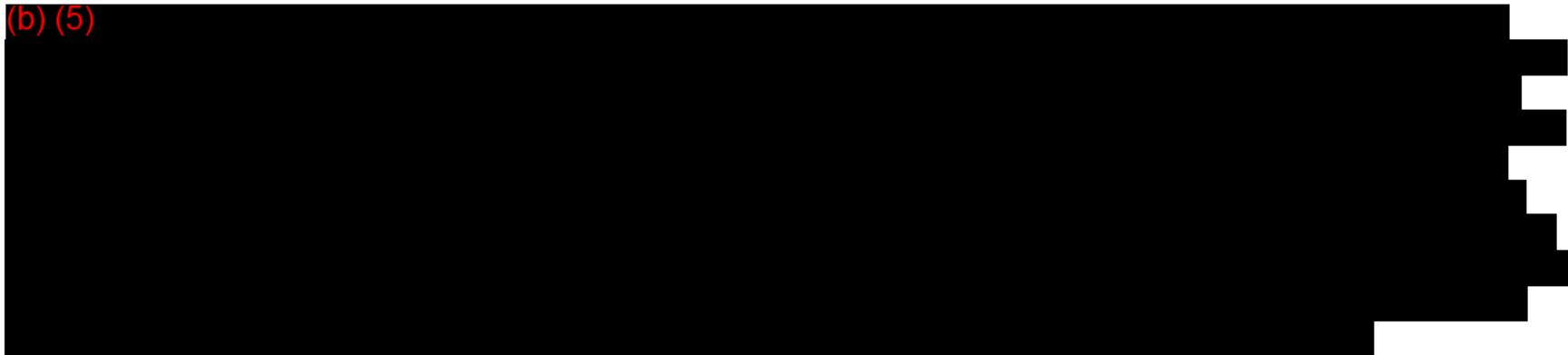
Workgroup to Address Ethylene Oxide Issues

(b) (5)

[Evaluator note: After the meeting, (b)(6) provided us with the key dates in the development of the 2014 NATA. See Source A.]

Prepared by:	Date
Bao Chuong	5/15/19
Approved by:	Date
Renee McGhee-Lenart	5/16/19

(b) (5)




**What Other Regions Are Doing to Address Ethylene Oxide Emissions**

(b) (5)



(b) (5)



Prepared by:	Date
Bao Chuong	5/15/19
Approved by:	Date
Renee McGhee-Lenart	5/16/19

(b)(6)

#### Upcoming Revision to NESHAP for Ethylene Oxide Commercial Sterilizers

(b)(6)

#### **B** [Link](#); [Link](#); [Link](#): Regional Applied Research Effort (RARE) to Improve Detection Limit of Ethylene Oxide

(b) (5)

[After the

meeting, (b)(6) provided us with the following related to the RARE proposal:

- RARE proposal (Source B)
- RARE project communicate plan (Source C)
- RARE project fact sheet (Source D)]

#### List of Ethylene Oxide-Emitting Facilities to Focus On

[Link](#): (b) (5)

[After the

meeting, (b)(6) provided us with the following related to the list of ethylene oxide-emitting facilities that OAQPS wanted regions to focus on:

Prepared by:	Date
Bao Chuong	5/15/19
Approved by:	Date
Renee McGhee-Lenart	5/16/19

- Forwarded 7/30/18 email (Source I) with list of facilities – (b) (5)
- Forwarded 8/1/18 email from (b) (6) on steps to address ethylene oxide-emitting facilities, (b) (5)  
(Source E)
- Email about the 8/8/18 (b) (5)  
(Source G)
- Email from (b) (5) (Source H)
- 8/13/18 (b) (5)  
(Source L)]

Reviewer Comment (and Date of Review)	Team Response (and Date of Response)	Resolution (and Date of Resolution)
		WP approved. RML 5/16/19

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	5/15/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	5/16/19

Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources  
OA&E-FY19-0091  
WP H.02.g

**PURPOSE:** To interview (b)(6) and (b)(6) regarding Region 5's role in addressing ethylene oxide emissions.

**SCOPE:** Interviewed (b)(6) and (b)(6) regarding Region 5's role in addressing ethylene oxide emissions.

**SOURCE:** A) (b)(6) notes (b)(6) took in meetings/briefings that took place June 20, 21, and 22, 2018 (b)(6)

B) 8/20/18 email from (b)(6), (b)(5)

C) 8/21/18 email showing (b)(6) (b)(5)  
(b)(6)

D) 8/22/18 revised Region 5 desk statement (b)(6), (b)(5)

E) 8/22/18 email showing final approved desk statement (b)(6), (b)(5)

F) 8/22/18 email showing that (b)(6), (b)(5)  
(b)(6)

G) 8/22/18 email showing (b)(6), (b)(5) (b)(6)

H) Draft talking points provided to (b)(6) for the 8/29/18 public meeting in Willowbrook. (b)(6)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	5/30/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/03/19
	No comments.



l) See the list of meeting participants below.

**DATE and TIME:** 4/4/19, 9:00 – 11:00 AM CDT.

**LOCATION:** Region 5 Office in Chicago, (b) (6).

**PARTICIPANTS:**

Region 5

(b)(6)  
(b)(6)

OIG – Office of Audit and Evaluation – Air Directorate  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy points from the interview included:

- (b) (5)
- The Region 5 Sterigenics website went live at about the same time that the 2014 NATA website went live. About an hour later, (b) (6), (b) (5)  
The Sterigenics website was back online in October 2018.

Prepared by:	Date
Bao Chuong	5/30/19
Approved by:	Date
Renee McGhee-Lenart	6/03/19
	No comments.

- (b) (5)

**DETAILS:**

After introductions, Renee provided a brief background on the OIG's Office of Audit and Evaluation and the Air Directorate. She then discussed the main air toxics Risk and Technology Review (RTR) assignment and that we had a kickoff meeting with OAQPS back in February. Then we received four Congressional requests. Our management decided that we would address the Congressional requests. Instead of having a separate assignment on the Congressional requests, our management decided to incorporate the Congressional requests into the main RTR assignment. Renee then read out the three Congressional questions we are addressing:

- Whether EPA senior political appointees instructed EPA inspectors to avoid conducting inspections at ethylene oxide emitting facilities across EPA Regions 5 and 6.
- Have inspections by the EPA been conducted on [ethylene oxide-emitting] facilities in Regions 5 and 6? If not, why?
- Whether the EPA complied with all statutory, regulatory and policy requirements and protocols in disclosing public health information about ethylene oxide air emissions from the Sterigenics facility in DuPage County, Illinois, the Medline Industries, Inc. facility in Lake County, Illinois and the Vantage Specialty Chemicals, Inc. facility in Lake County, Illinois.

We then discussed the following topics.

Background on (b)(6)

(b)(6)

Prepared by:	Date
Bao Chuong	5/30/19
Approved by:	Date
Renee McGhee-Lenart	6/03/19
	No comments.

(b)(6)

(b)(6)

#### Region 5 Air and Radiation Division Briefing to Office of the Regional Administrator About Results of the May 2018 Monitoring at Sterigenics

(b) (6) explained that there were a couple of briefings on June 20, 2018 based on (b) (6) notes (see Source A (b) (6)):

- 6/20/18 morning. (b) (5)  
(b) (5)
- A [Link: Link:](#) 6/20/18, 2:30pm. Meeting on Sterigenics. Regional Administrator Cathy Stepp was at the meeting. (b) (5), (b) (6)  
(b) (5), (b) (6)

Prepared by:	Date
Bao Chuong	5/30/19
Approved by:	Date
Renee McGhee-Lenart	6/03/19
	No comments.

(b) (6), (b) (5)

#### Preparations for the Release of the 2014 NATA to the Public

(b) (6) that on August 20, 2018, there was an email from HQ press people letting us know that ATSDR was going to release the letter health consultation on Sterigenics the next day and that HQ was going to release the 2014 NATA soon after. (b) (6), (b) (5)

Prepared by:	Date
Bao Chuong	5/30/19
Approved by:	Date
Renee McGhee-Lenart	6/03/19
	No comments.

(b) (5)

Source E shows the final approved desk statement on Sterigenics.

#### Release of the 2014 NATA to the Public

(b) (5)

**B** [Link:](#) [Link:](#) (b) (5)

Prepared by:	Date
Bao Chuong	5/30/19
Approved by:	Date
Renee McGhee-Lenart	6/03/19
	No comments.

(b) (5)

October was when the Sterigenics website was back live. The October website was very similar to what was live on 8/22/18.

(b) (6), (b) (5)

#### 8/29/18 Public Meeting in Willowbrook

(b)(6) explained that even though the Region 5 Sterigenics website was taken down, the Willowbrook mayor had already seen the website before it was taken down and read the ATSDR letter health consultation on Sterigenics. [A Link:Link:Link:Link](#) (b) (5)

Region 5's Cathy Stepp, Jim Payne, Ed Nam, Rachel Bassler Linduska (press officer), and Jeff Kelly were at the meeting. (b) (6), (b) (5)

There were 600 people at meeting and 200 watching the live stream. After introductory remarks by the mayor. Bill Foster started with written questions, but people began yelling out questions.

Prepared by:	Date
Bao Chuong	5/30/19
Approved by:	Date
Renee McGhee-Lenart	6/03/19
	No comments.

(b)(6) said that besides Region 5, ATSDR, Illinois EPA, and Sterigenics were also at the meeting. The front panel consisted of ATSDR's Mark Johnson and Michelle Colledge, Kathy Hoffman of Sterigenics and a person from Willowbrook, Cathy Stepp, Ed Nam, and Alec Messina of Illinois EPA.


(b) (5)



(b) (5)



(b) (6), (b) (5)



Prepared by:	Date
Bao Chuong	5/30/19
Approved by:	Date
Renee McGhee-Lenart	6/03/19
	No comments.

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.02.h**

**PURPOSE:** To interview (b)(6) and (b)(6) regarding Region 5's role in addressing ethylene oxide emissions.

**SCOPE:** Interviewed (b)(6) and (b)(6) regarding Region 5's role in addressing ethylene oxide emissions.

**SOURCE:** A) May 31, 2017 OECA memo on Interim Procedures for Issuing Information Requests Pursuant to Clean Air Act § 114, Clean Water Act § 308, and RCRA § 3007. (b) (6) )

B) November 16, 2018 OECA memo on Best Practices for Compliance and Enforcement-Related Information Requests, which supersedes Source A. (b) (6)

C) September 15, 1983 guidance on the use of CAA Section 303 to shut down a facility. (b) (6) )

D) September 5, 2018 memo from (b)(6) on (b) (5) (b) (6) Please note this document is ATTORNEY CLIENT PRIVILEGED; ATTORNEY WORK PRODUCT; AND ENFORCEMENT CONFIDENTIAL. DO NOT RELEASE UNDER FOIA.

E) 2/11/19 forwarded email from (b)(6) (b) (5) (b) (6) Please note this document is ATTORNEY CLIENT PRIVILEGED; ATTORNEY WORK PRODUCT; AND ENFORCEMENT CONFIDENTIAL. DO NOT RELEASE UNDER FOIA.

F) 2/8/19 (b) (6) email to (b)(6) with (b) (6), (b) (5) (b) (6) Please note this document is ATTORNEY CLIENT PRIVILEGED; ATTORNEY WORK PRODUCT; AND ENFORCEMENT CONFIDENTIAL. DO NOT RELEASE UNDER FOIA.

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	5/30/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/4/19



G) 2/8/19<sup>(b)(6)</sup> email to (b) (6), regarding the 2/7/19 meeting (b) (5)  
(b) (6) (b) (6) Please note this document is ATTORNEY  
CLIENT PRIVILEGED; ATTORNEY WORK PRODUCT; AND ENFORCEMENT CONFIDENTIAL. DO NOT RELEASE UNDER FOIA.

H) 2/8/19 email showing (b) (5), (b) (6)  
(b) (6) Please note this document is ATTORNEY CLIENT  
PRIVILEGED; ATTORNEY WORK PRODUCT; AND ENFORCEMENT CONFIDENTIAL. DO NOT RELEASE UNDER FOIA.

I) 2/5/19 email from (b) (6), (b) (5) (b) (6) Please note this  
document is ATTORNEY CLIENT PRIVILEGED; ATTORNEY WORK PRODUCT; ENFORCEMENT CONFIDENTIAL; AND  
DELIBERATIVE. DO NOT RELEASE UNDER FOIA.

J) Early draft of briefing document on federal and state authorities (b) (5) (b) (6)  
Please note this document is ATTORNEY CLIENT PRIVILEGED; ATTORNEY WORK PRODUCT; ENFORCEMENT  
CONFIDENTIAL; AND DELIBERATIVE. DO NOT RELEASE UNDER FOIA.

K) Briefing document on federal and state authorities (b) (5)  
(b) (6) Please note this document is ATTORNEY CLIENT PRIVILEGED; ATTORNEY WORK  
PRODUCT; AND ENFORCEMENT CONFIDENTIAL. DO NOT RELEASE UNDER FOIA.

L) 2/12/19 Email from (b) (6) transmitting the briefing document on federal  
and state authorities (b) (5) (b) (6) Please note this  
document is ATTORNEY CLIENT PRIVILEGED; ATTORNEY WORK PRODUCT; AND ENFORCEMENT CONFIDENTIAL. DO NOT  
RELEASE UNDER FOIA.

M) 3/6/19 email from (b)(6) to (b) (6) (b) (5)  
(b) (6) Please note this document is ATTORNEY CLIENT

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	5/30/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/4/19

PRIVILEGED; ATTORNEY WORK PRODUCT; ENFORCEMENT CONFIDENTIAL; AND DELIBERATIVE. DO NOT RELEASE UNDER FOIA.

N) 2/5/19 email showing (b) (6), (b) (5)  
(b) (6) Please note this document is ATTORNEY CLIENT PRIVILEGED; ATTORNEY WORK PRODUCT; AND ENFORCEMENT CONFIDENTIAL. DO NOT RELEASE UNDER FOIA.

O) 3/7/19 email from (b)(6) to (b) (6) (b) (5)  
(b) (6) Please note this document is ATTORNEY CLIENT PRIVILEGED; ATTORNEY WORK PRODUCT; AND ENFORCEMENT CONFIDENTIAL. DO NOT RELEASE UNDER FOIA.

P) 42 USC 7403 (<https://www.law.cornell.edu/uscode/text/42/7403>, accessed 5/21/19)

Q) February 2019 emails (b) (5)  
(b) (6) Please note this document is ATTORNEY CLIENT PRIVILEGED; ATTORNEY WORK PRODUCT; AND ENFORCEMENT CONFIDENTIAL. DO NOT RELEASE UNDER FOIA.

R) 4/5/19 email from (b) (6) Please note this document is ATTORNEY CLIENT PRIVILEGED; ATTORNEY WORK PRODUCT; AND ENFORCEMENT CONFIDENTIAL. DO NOT RELEASE UNDER FOIA.

S) See the list of meeting participants below.

DATE and TIME: 4/4/19, 11:00 AM – 12:30 PM CDT.

LOCATION: (b) (6).

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	5/30/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/4/19

**PARTICIPANTS:**

**Region 5**

(b)(6)

(b)(6)

(b) (6)

OIG – Office of Audit and Evaluation – Air Directorate  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy points from the interview included:

- (b) (5), (b) (6)

Prepared by:	Date
Bao Chuong	5/30/19
Approved by:	Date
Renee McGhee-Lenart	6/4/19

DETAILS:

(b)(6) (b) (6)  
The following topics were discussed.

Background on (b) (6)

(b) (6) (b) (6)

(b)(6)

Ele

(b) (6) (b) (5) . In December 2017, (b) (6) sent a letter to Ele about the modeling results and the need to get accurate emissions data and modeling parameters from Ele. (b) (5) (b) (5)

Prepared by:	Date
Bao Chuong	5/30/19
Approved by:	Date
Renee McGhee-Lenart	6/4/19

(b) (5)

[Evaluator note: (b) (6)]

- May 31, 2017 OECA interim procedures for issuing information requests pursuant to Clean Air Act Section 114, Clean Water Act Section 308, and RCRA Section 3007. (Source A)
- November 16, 2018 OECA memo on Best Practices for Compliance and Enforcement-Related Information Requests (Source B) which supersedes Source A.]

(b) (5), (b) (6)

(b) (6), (b) (5)

(b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	5/30/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/4/19

(b) (6), (b) (5)

[Redacted]

(b) (6), (b) (5)

(b) (6)

(b) (5)

EPA Authority to Conduct Monitoring of Sterigenics

(b) (5)

(b) (6), (b) (5)

(b) (6), (b) (5)

Prepared by:	Date
Bao Chuong	5/30/19
Approved by:	Date
Renee McGhee-Lenart	6/4/19

Drafting of CAA Section 114 Letter (b) (5)


(b) (6), (b) (5)

Briefing Document on Federal and State Authorities (b) (5)

(b) (6), (b) (5)

Prepared by:	Date
Bao Chuong	5/30/19
Approved by:	Date
Renee McGhee-Lenart	6/4/19

(b) (6), (b) (5)



(b) (6), (b) (5)

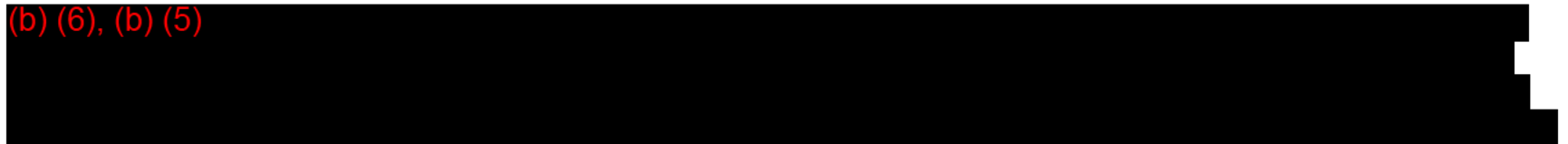

(b) (6), (b) (5)


(b) (5)



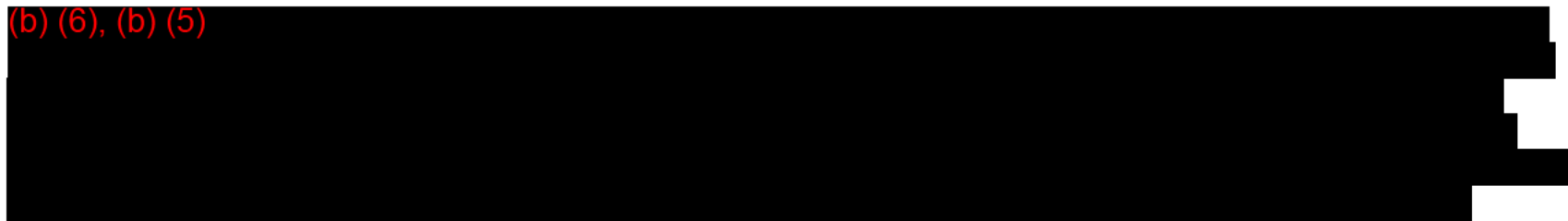
(b) (6), (b) (5)




Prepared by:	Date
Bao Chuong	5/30/19
Approved by:	Date
Renee McGhee-Lenart	6/4/19




(b) (6), (b) (5)



Whether Region 5 Should Have (b) (5)




(b) (6), (b) (5)



Whether There Are Any Statutory, Regulatory, Policy, or Protocol Requirements for EPA to Disclose Health Information to the Public As It Relates to CAA


(b) (6), (b) (5)



Prepared by:	Date
Bao Chuong	5/30/19
Approved by:	Date
Renee McGhee-Lenart	6/4/19

Other Matters

(b) (6), (b) (5)

A large rectangular area of the document is completely redacted with black ink. To the left of this redacted area, there are three vertical black bars, likely representing bullet points or list markers. The redaction covers approximately 80% of the page's content area.

Prepared by:	Date
Bao Chuong	5/30/19
Approved by:	Date
Renee McGhee-Lenart	6/4/19

Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources  
OA&E-FY19-0091  
WP H.02.m

**PURPOSE:** To follow up with (b)(6) regarding (b) (5).

**SCOPE:** Spoke to (b) (6) regarding (b) (5).

**SOURCE:** A) See the list of meeting participants below.

**DATE and TIME:** 4/24/19, 8:00 – 8:30 AM PDT.

**LOCATION:** Telephone call.

**PARTICIPANTS:**

(b)(6)  
(b)(6)

OIG, Office of Audit and Evaluation, Air Directorate  
Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one phone call.

**SUMMARY:** Noteworthy points from the phone call included:

- (b) (5), (b) (6)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/20/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/20/19

(b) (5), (b) (6)

**DETAILS:**

(b) (5), (b) (6)

(See H.02.h > Source N > Pg. 2 of

5 [Link:](#) ) (b) (6), (b) (5)

Below are the

questions asked (black text) and (b)(6) response (blue text).

1. (b) (6), (b) (5)

2. We understand that Region 5's Air and Radiation Division has been very proactive in addressing ethylene oxide emissions. (b) (5)

inspect (b) (5) any other ethylene oxide-emitting facilities?

(b) (5), (b) (6)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/20/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/20/19

(b) (6), (b) (5)

3. Did someone from OECA or OAR tell you that you must talk to the state first before conducting an inspection?

(b) (6), (b) (5)

4. How are you going about addressing potential non-notifiers of ethylene oxide emissions?

(b) (6), (b) (5)

(b) (6)

(b) (5)

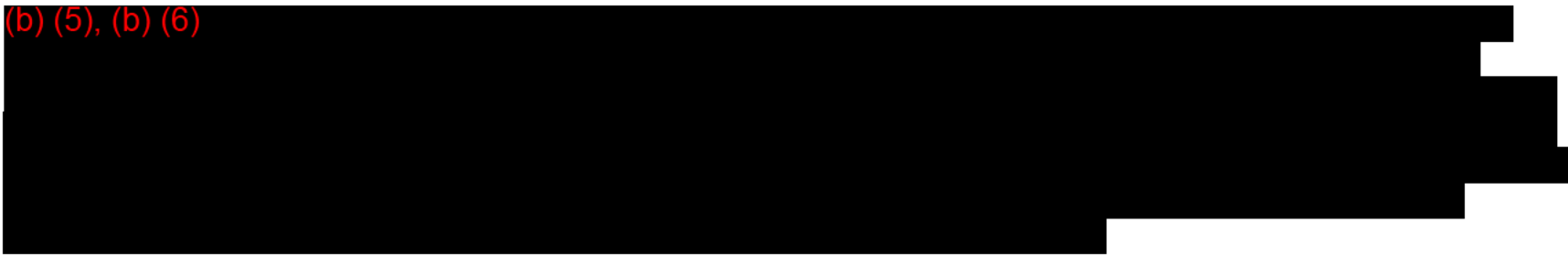
5. (b) (6), (b) (5)

(b) (5)

6. Have you heard OAR or anyone else telling regions not to inspect (b) (5) or any other ethylene oxide-emitting facilities

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/20/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/20/19

(b) (5), (b) (6)



Reviewer Comment (and Date of Review)	Team Response (and Date of Response)	Resolution (and Date of Resolution)
Reviewed by RML 6/20/19 No comments.		WP approved. RML 6/20/19

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/20/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/20/19

Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources

OA&E-FY19-0091

WP H.02.n

**PURPOSE:** To interview (b)(6) regarding EPA's role in addressing ethylene oxide emissions.

**SCOPE:** Interviewed (b)(6) regarding EPA's role in addressing ethylene oxide emissions.

**SOURCE:** A) ADP tracker for HCl production RTR (b) (6)

B) 5/9/19 email from (b)(6) confirming ADP workgroup members.

C) See the list of meeting participants below.

**DATE and TIME:** 5/6/19, 9:00 AM – 9:45 AM EDT.

**LOCATION:** (b) (6).

**PARTICIPANTS:**

(b)(6)

OIG – Office of Audit and Evaluation – Air Directorate  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/11/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/12/19
No comments.	

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy points from the interview included:

- (b) (5), (b) (6)

**DETAILS:**

After introductions, Renee explained that we started the air toxics RTR assignment with a kickoff meeting in February. Our management then wanted us to address Congressional requests. Renee noted the three Congressional questions we are currently addressing:

- (1) Whether EPA senior political appointees instructed EPA inspectors to avoid conducting inspections at ethylene oxide-emitting facilities across EPA Regions 5 and 6.
- (2) Have inspections by the EPA been conducted on [ethylene oxide-emitting] facilities in Regions 5 and 6? If not, why?
- (3) Whether the EPA complied with all statutory, regulatory and policy requirements and protocols in disclosing public health information about ethylene oxide air emissions from the Sterigenics facility in DuPage County, Illinois, the Medline Industries, Inc. facility in Lake County, Illinois and the Vantage Specialty Chemicals, Inc. facility in Lake County, Illinois.

Renee then proceeded to ask the following questions. Blue texts were (b)(6) responses.

Background on (b)(6)

1. What is your title or role in (b) (6)

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
No comments.	



(b)(6)

2. How long have you been in your current position?

(b) (6)

3. Who do you report to?

(b) (6)

#### Current NESHAP for Hydrochloric Acid (HCl) Production

4. Please provide a high-level overview of the current NESHAP for hydrochloric acid production.

(b) (6), (b) (5)

#### RTR for HCl Production

5. [Link:](#) **A** Please provide an overview of the RTR conducted for HCl production, including the results of the RTR.

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
No comments.	

(b) (6), (b) (5)

6. The February 4, 2019 proposed rule for the HCl production RTR stated that “the maximum facility-wide cancer Maximum Individual Risk (MIR) is 600 in one million, mainly driven by ethylene oxide emissions from a variety of industrial processes, none of which are part of this source category.” Of the 19 facilities that are subject to the NESHAP for HCl production, how many of them engage in processes that emit ethylene oxide?

(b) (5)

This is based on the National Emissions Inventory (NEI). (b) (5)

- a. How many of these ethylene oxide-emitting facilities are subject to the NESHAP for HON?

(b) (5)

- b. How many of these ethylene oxide-emitting facilities are subject to the NESHAP for MON?

(b) (5)

- c. How many of these ethylene oxide-emitting facilities are subject to the NESHAP for polyether polyols production?

(b) (5)

- d. Could we get a list of the HCl production facilities that are engaged in processes that emit ethylene oxide?

Yes.

- e. Are there any previous RTRs where the maximum facility-wide cancer MIR is 100 in one million or greater? If so, how did OAQPS address this risk to bring it down to below 100 in one million?

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
No comments.	

(b) (5)

7. The proposed rule for the HCl production RTR stated that “the EPA is interested in receiving public comments on the use of the update[d] risk value for regulatory purposes.” This is in reference to the updated risk value for ethylene oxide issued by the IRIS program. Why was this statement included in the proposed rule?

(b) (5)

(b) (6), (b) (5)

- a. Have there been any new scientific studies since December 2016 that suggest ethylene oxide is not as potent in cancer toxicity as the IRIS program had concluded? If so, please provide us with a list of the new scientific studies.

(b) (5)

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
No comments.	

b. (b) (6), (b) (5)

c. (b) (6), (b) (5)

d. (b) (6)

[See response before Question 7a.](#)

e. Does OAQPS have the authority to use a risk value different than what the IRIS program issued for regulatory purposes?

(b) (5).

f. If someone from the public has reservations about an IRIS-issued risk value, isn't the appropriate recourse to file a Request for Correction (RFC) with the IRIS program under the Information Quality Act? If so, why did the proposed rule include the statement on collecting comments on the use of the IRIS-issued updated risk value for ethylene oxide?

(b) (6), (b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/11/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/12/19
No comments.	

(b) (5), (b) (6)

8. The proposed rule noted that EPA intends to evaluate those facility-wide estimated emissions and risks further and may address these in a separate future action, as appropriate.

- a. Given that the estimated cancer MIR is 600 in one million, isn't it EPA's policy to take action because it's above the threshold of 100 in one million?

(b) (5).

- b. Are there any plans to reopen or redo the RTR for HON and RTR for polyether polyols production? If so, have ADP actions started for these RTRs?

(b) (5).

#### Process to Reopen or Redo an RTR

9. Does OAQPS have a process to reopen or redo an RTR whenever there is new information, such as a new IRIS assessment, that call into question the protectiveness of existing NESHAP standards?

(b) (5).

10. Does OAQPS have a process to reopen or redo an RTR that is driving the maximum facility-wide cancer MIR above 100 in one million?

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
No comments.	

(b) (5)

#### RTRs That Have Concluded Existing NESHAP Not Providing Ample Margin of Safety

11. We have not reviewed all RTRs that have ever been conducted, but the ones that we have looked at all conclude existing NESHAPs provide ample margin of safety to protect public health. Thus, no changes to existing NESHAPs are warranted. (b) (5)

(b) (5), (b) (6)

12. How would OAQPS set standards to bring residual risk below 100 in one million if the technology is not available to bring the risk down? Would the standard be to limit facility operation (e.g., instead of operating 24 hours, facilities must not operate more than 12 hours per day)?

(b) (6), (b) (5)

#### Comments on the Proposed Rule

13. We understand that comments on the proposed rule for the HCl production RTR were due on March 21, 2019.
- a. Were there any comments regarding the use of a lower risk value for ethylene oxide for regulatory purposes? If so, were the majority of the comments in favor of retaining the updated IRIS-issued risk value for ethylene oxide?

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
No comments.	

Public comment period was extended till April 26, 2019. I believe (b) (6), (b) (5)

[REDACTED]

b. Does OAQPS intend to use a different risk value for ethylene oxide in future regulations?

Public comment period has not ended yet (b) (6), (b) (5)

[REDACTED]

14. Where in the ADP process is the action at right now?

Public comment period was extended to April 26, 2019. Typically, the process after a proposed rule is published, is that public comments are collected. Once public comment closes, we would review the comments and summarize the comments. Based on the comments, we propose options to management. Management selects an option. Final rule is then published. (b) (6), (b) (5)

[REDACTED]

a. When will the final rule be issued? Will it meet the court-ordered deadline of March 13, 2020?

(b) (5)

[Evaluator note: We requested and received the ADP tracker for the HCl production RTR proposed rule, (See Source A) which shows the final rule is scheduled to meet the court-ordered deadline of 3/13/20. (Source A > Pg. 2 of 6 > Section "Deadlines")]

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
No comments.	

b. Will the final rule include the issuance of a new risk value for ethylene oxide for future regulations?

(b) (6), (b) (5)

#### Directives

15. Do you have knowledge of the following HQ directives or heard of the following HQ directives in any sterilizer workgroup calls or anywhere else?

- Directive not to do inspections at ethylene oxide facilities - (b) (6)
- Directive not to do monitoring at ethylene oxide facilities - (b) (5)
- Directive not to do modeling at ethylene oxide facilities - (b) (5)
- Directive for Region 5 not to work with ATSDR - (b) (5)
- Directive not to release the May 2018 monitoring data at Sterigenics in June 2018 - (b) (6)
- Directive not to send 114 letters to ethylene oxide facilities - (b) (5)

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
No comments.	



**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.02.o**

**PURPOSE:** To interview (b)(6) regarding EPA's role in addressing ethylene oxide emissions.

**SCOPE:** Interviewed (b)(6) regarding EPA's role in addressing ethylene oxide emissions.

**SOURCE:** A) See the list of meeting participants below.

**DATE and TIME:** 5/6/19, 1:00 – 2:00 PM EDT.

**LOCATION:** (b) (6).

**PARTICIPANTS:**

(b)(6)

OIG – Office of Audit and Evaluation – Air Directorate  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy [Link](#): WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docxpoints from the interview included:

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/11/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/12/19
No comments.	

•  
i

(b) (6), (b) (5)

**DETAILS:**

After introductions, the following questions were asked. (b)(6) responses are in blue text.

Background on (b)(6)

(1) What is your title or role in (b) (6)

(b)(6)

(2) When did you become involved in the monitoring of ethylene oxide facilities after the IRIS value for ethylene oxide was revised in December 2016?

(b) (6)

**Sterigenics Monitoring and Public Communication and Involvement with Other EtO Facilities**

(3) What has been your involvement in the monitoring of Sterigenics?

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
No comments.	

(b) (5), (b) (6)

(b) (6), (b) (5)

(b) (6), (b) (5)

- a. Who did you work with in HQ, OAQPS, and Region 5 regarding this facility? [See response above.](#)
- b. Were you involved with the May 2018 monitoring that took place? If so, please describe. [See response above.](#)
- c. Why did monitoring not resume until November 2018 after the initial monitoring took place in May 2018?

(b) (6), (b) (5)

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
No comments.	

d. How did the discovery about (b) (5) affect your monitoring plans? Has this been resolved?

(b) (6), (b) (5)

e. Does EPA need better monitoring techniques to monitor and assess ethylene oxide emissions? (Workgroup)

(b) (5)

(4) How would you characterize the November 2018 to March 2019 monitoring results?

(b) (5)

a. Given the results of the ambient monitoring of Sterigenics, do you see value in conducting ambient monitoring of ethylene oxide despite the current detection limit? Why or why not?

(b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/11/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/12/19
No comments.	

(b) (5)

(b) (5)

(b) (5)

- b. The 4.5 months of ambient monitoring conducted between November 2018 and March 2019 at Sterigenics showed that ethylene oxide concentrations were generally higher than before the back vent emissions were controlled. What do you think is the reason for the higher than expected ambient concentrations?

(b) (5)

(b) (5)

(b) (5)

- (5) According to EPA's website on Sterigenics, EPA will release a revised risk assessment of the area around Sterigenics. What is the status of that revised risk assessment?

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
No comments.	

(b) (5)

(6) What has been your role in reaching out to the public in Willowbrook, IL?

(b) (6), (b) (5)

a. Did OAQPS take over the role of communicating with the public about Sterigenics? Is so, why?

(b) (5)

b. How did the public react to the monitoring results?

(b) (5)

(b) (5)

(b) (5)

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
No comments.	

(b) (5)

(b) (5)

on February 15, State of Illinois issued a seal order, shutting down Sterigenics.

(b) (5)

(7) Are you involved in monitoring or providing advice on monitoring at any other ethylene oxide facilities such as Medline, Vantage Specialty Chemicals, or Ele? If so, please describe.

(b)(6)

(b) (5)

(b) (6)

#### Directives

(8) We have some questions about HQ directives. Do you have knowledge of the following?

We would like to know the following:

- (1) When was the meeting held/email received that provided the following directive.
- (2) Who was in the meeting or on the email chain?
- (3) Who did the directive come from?
- (4) What was the reason for the directive?

- Directive not to do inspections at ethylene oxide facilities

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
No comments.	

(b) (6), (b) (5)

- Directive not to do monitoring at ethylene oxide facilities

(b) (6)

- Directive not to do modeling at ethylene oxide facilities

(b) (6), (b) (5).

- Directive for Region 5 not to work with ATSDR

(b) (6), (b) (5).

- Directive not to release the May 2018 monitoring data at Sterigenics in June 2018

(b) (6), (b) (5)

- Directive not to send 114 letters to ethylene oxide facilities.

(b) (6), (b) (5)

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
No comments.	



(b) (5)

(b) (5)

(b) (5)

#### EPA No Longer Interested in Conducting Ambient Monitoring of EtO Facilities

- (9) What is EPA's position on conducting ambient monitoring of ethylene oxide facilities? Does EPA believe that monitoring should be conducted when modeling shows elevated cancer risks? Why or why not?

(b) (5)

#### List of 25 Facilities that Contribute to Elevated Cancer Risks

- (10) We heard that OAQPS distributed a list of 25 facilities that contributed to elevated cancer risks to the regions for them to focus on.
- a. What is OAQPS or HQ's expectations of the regions with respect to these 25 facilities? Were these expectations written and sent to the regions?

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
No comments.	

[Link: WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docx](#) (b) (5)

b. What milestones were associated with these expectations?

[Link: WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docx](#)ASAP. (b) (5)

- (11) We understand that one of the criteria for facilities to get listed was if they contributed to a cancer risk of  $\geq 1,000$  in one million at the census block level. We understand that it has been a long-standing EPA policy that a risk of 100 in 1,000,000 does not provide an ample margin of safety. Why was a cancer risk of  $\geq 1,000$  in one million at the census block level selected?

(b) (5)

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
No comments.	

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.02.p**

**PURPOSE:** To interview (b)(6) regarding EPA's role in addressing ethylene oxide emissions.

**SCOPE:** Interviewed (b)(6) regarding EPA's role in addressing ethylene oxide emissions.

**SOURCE:** A) See the list of meeting participants below.

**DATE and TIME:** 5/6/19, 2:00 – 3:00 PM EDT.

**LOCATION:** (b) (6) .

**PARTICIPANTS:**

(b)(6)

**OIG – Office of Audit and Evaluation – Air Directorate**  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy points from the interview included:

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
A few minor changes were made.	

- (b) (5), (b) (6)
- [REDACTED]

**DETAILS:**

After introductions, the following questions were asked. (b) (5), (b) (6) responses are in blue text.

Background on (b)(6)

1. What is your title or role in (b) (6)

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
A few minor changes were made.	

(b)(6)

2. How long have you been in your current position?

(b) (6)

3. Are you a career civil servant? Or a political appointee?

Career.

4. Who do you report to?

(b)(6)

5. How did you become tasked with (b) (6) ?

This project cuts across multiple divisions and requires coordination.

(b) (5)

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
A few minor changes were made.	

(b) (5)

6. (b) (6)

a. (b) (6)

#### Two-Pronged Approach

7. Provide us some background on how the two-pronged approach was developed and what the goals of the strategy are?

[Link: A](#) (b) (5)

(b) (5)

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
A few minor changes were made.	

(b) (5)

[Link: WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docx](#)Regarding Prong 2 (b) (5)

[Link: B](#)(b) (5)

Sterigenics and the Release of NATA

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
A few minor changes were made.	

8. As you know, Region 5, with assistance from OAQPS, conducted ambient monitoring of Sterigenics in Willowbrook, Illinois in May 2018.

(b) (6), (b) (5)

- a. (b) (6), (b) (5)

9. We understand that Region 5 had a webpage on Sterigenics that went live while the 2014 NATA webpage went live. We also understand that the Region 5 webpage on Sterigenics was live for about an hour (b) (6), (b) (5)

[C Link:](#) (b) (5)

(b) (5)

(b) (6)

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
A few minor changes were made.	



(b) (6) [REDACTED] ?

(b) (5) [REDACTED]

[REDACTED]

#### Communication with Sterigenics

10. (b) (6), (b) (5) [REDACTED]

[REDACTED]

[REDACTED]

11. Why was this done?

[See response to Question 10.](#)

12. **E** [Link](#): Why was there a delay in additional monitoring from May 2018 to November 2018?

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
A few minor changes were made.	

(b) (5)

[REDACTED]

[REDACTED]

13. What communication or data have you received from Sterigenics in 2019?

(b) (6), (b) (5)

[REDACTED]

(b) (5)

[REDACTED]

14. What type of communication with the public has taken place since OAR has taken over responsibility for the facility?

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
A few minor changes were made.	

Webinars. End of November had public meeting. (b) (5), (b) (6)

#### Directive Not to Conduct Inspections or Take Enforcement Actions

15. Do inspections and enforcement come into play in the two-pronged strategy to address ethylene oxide emissions?

(b) (5)

a. We had heard that Region 5 was directed not to conduct inspections unless they were invited by a state to conduct a joint inspection.

i. Who issued the directive?

(b) (5)

ii. Why was the directive issued? Did not ask. See response to 15.a.i.

iii. Was the same directive issued to other regions? Did not ask. See response to 15.a.i.

b. How is EPA going to address (b) (5) ?

(b) (5)

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
A few minor changes were made.	

(b) (5)

#### Directive Not to Send CAA Section 114 Letters to Facilities

16. We understand that the second prong of the two-pronged approach to address ethylene oxide emissions involves gathering information. However, we learned that Region 5 staff were told not to issue Section 114 letters to ethylene oxide facilities.

a. Who issued the directive? (b) (5)

b. Why was the directive issued? [See response to Question 16a.](#)

c. Was the same directive issued to other regions? (b) (5) .

(b) (5)

#### Directive to Get Permission from OAQPS to Conduct Modeling

17. [G Link](#): We heard that Region 5 was told to seek permission from OAQPS before conducting any modeling on ethylene oxide facilities.

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
A few minor changes were made.	

a. Who instructed Region 5 to get permission from OAQPS to conduct modeling? (b) (5)

b. Why was this instruction given to Region 5? [See response to Question 17a.](#)

c. Was the same instruction given to other regions? [See response to Question 17a.](#)

#### Directive Not to Conduct Monitoring

18. **D** [Link](#): We understand that OAQPS recently completed ambient monitoring of Sterigenics in Willowbrook. We also heard that the agency won't be conducting monitoring of ethylene oxide emissions from other facilities.

(b) (5)

a. Whose decision was it that EPA won't be conducting monitoring of ethylene oxide emissions from other facilities?

(b) (5)

b. What was the reasoning for this decision? (b) (5)

#### Directive Not to Seek the Assistance from ATSDR

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
A few minor changes were made.	

(b) (5), (b) (5)

[REDACTED]

[REDACTED]

#### List of 25 Facilities that Contribute to Elevated Cancer Risks

20. We heard that OAQPS distributed a list of 25 facilities that contributed to elevated cancer risks to the regions for them to focus on.

- a. What is OAQPS or HQ's expectations of the regions with respect to these 25 facilities? Were these expectations written and sent to the regions?

[Link: WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docx](#) (b) (5)

[REDACTED]

- b. What milestones were associated with these expectations?

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
A few minor changes were made.	

Link: WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docx (b) (5)

(b) (6), (b) (5)

21. We understand that one of the criteria for facilities to get listed was if they contributed to a cancer risk of  $\geq 1,000$  in one million at the census block level. We understand that it has been a long-standing EPA policy that a risk of 100 in 1,000,000 does not provide an ample margin of safety. Why was a cancer risk of  $\geq 1,000$  in one million at the census block level selected?

Link: (b) (6), (b) (5)

[Evaluator

note: The list of 25 facilities consists of 22 facilities with at least 100 in 1,000,000 cancer risk at the census tract level and 3 facilities with at least 1,000 in 1,000,000 cancer risk at the census block level. See WP H.02.d > Source N [Link:](#) ]

(b) (5)

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
A few minor changes were made.	

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.02.r**

**PURPOSE:** To interview (b)(6) regarding EPA's role in addressing ethylene oxide emissions.

**SCOPE:** Interviewed (b)(6) regarding EPA's role in addressing ethylene oxide emissions.

**SOURCE:** A) 5/8/19 (b)(6) email response to follow-up questions.

B) ADP tracker for MON RTR ((b) (6) )

C) See the list of meeting participants below.

**DATE and TIME:** 5/7/19, 10:30 AM – 12:00 PM EDT.

**LOCATION:** (b) (6) .

**PARTICIPANTS:**

(b)(6)

OIG – Office of Audit and Evaluation – Air Directorate  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one meeting.

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/11/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/13/19
No comments.	



**SUMMARY:** Noteworthy points from the interview included:

- (b) (5), (b) (6)

█

█

█

**DETAILS:**

After introductions, the following questions were asked. (b) (6) responses are in blue text.

Background on (b)(6)

1. What is your title or role in (b) (6)

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/13/19
No comments.	

(b)(6)

2. How long have you been in your current position?

(b) (6)

3. Who do you report to?

(b) (6)

RTR for MON

4. Please provide a high-level overview of the current NESHAP for MON.

(b) (5)

MON covers the following processes: waste streams, heat exchanges, storage tanks, equipment leaks, process vents, and transfer operations.

5. Is the RTR for MON the result of a court order or consent decree?

Court order.

6. We understand that the court order deadline to issue the final rule is 3/13/20. Will OAQPS be able to meet this deadline?

(b) (5), (b) (6)

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/13/19
No comments.	

7. When did the Action Development Process (ADP) begin for the RTR for MON?

(b) (6), (b) (5)

a. (b) (6) ?

(b) (6), (b) (5)

b. (b) (6) ?

(b) (6), (b) (5)

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/13/19
No comments.	

(b) (6), (b) (5)

8. What is the current tier of the ADP action? (b) (6), (b) (5)

a. What is the reason for the current tier? (b) (5)

b. Did anyone in the ADP workgroup propose to up tier the action? (b) (5)

i. If so, what was the outcome of the up tier proposal? Not applicable. See response above.

9. How many ethylene oxide-emitting facilities are subject to MON? (b) (6), (b) (5)

10. How many non-ethylene oxide-emitting facilities are subject to MON? (b) (5)

11. **B** [Link](#): What data or information have (b) (6) collected to inform the MON RTR as it relates to ethylene oxide?

(b) (5)

a. Did you reach out to the ethylene oxide-emitting facilities for data or information?

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/13/19
No comments.	

i. If so, how did you reach out to the EtO facilities?

ii. Did you have to send out CAA Section 114 letters to EtO facilities?

**C** [Link:](#) [Link:](#) (b) (5)

[REDACTED]

b. What other stakeholders did (b) (6) reach out to as it relates to EtO? (e.g., Ethylene Oxide Sterilization Association, environmental advocacy groups) contacted regions and states to see if they have more info about these facilities.

(b) (6), (b) (5)

i. If so, what information did you ask from them? (b) (6), (b) (5)

12. Who in OAQPS is conducting the residual risk assessment for the MON RTR? (b) (6), (b) (5)

13. Please provide an overview of what you expect the conclusions of the MON RTR to be. (Auditor's Note: MON is a source category.)

**D** [Link:](#) (b) (5)

(b) (6), (b) (5)

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/13/19
No comments.	

- a. Is the risk assessment expected to conclude that the existing MON NESHAP provides or does not provide an ample margin of safety to protect public health?

(b) (5)

- b. If the risk assessment is expected to conclude that the existing MON NESHAP does not provide an ample margin of safety, is this conclusion due to the EtO-emitting facilities?

(b) (5)

- i. If so, what new controls, work practices, or other standards do you expect to propose?

(b) (6), (b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/11/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/13/19
No comments.	

- (b) (5), (b) (6)

(b) (6), (b) (5)

- ii. Will the new controls, work practices, or other standards be sufficient to decrease cancer risks? What evidence is there to support the decrease in cancer risks?

(b) (6), (b) (5)

14. Where in the ADP process is the MON RTR at right now?

(b) (5), (b) (6)

- a. Who in EPA will sign off on the upcoming proposed rule? (b) (6), (b) (5)

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/13/19
No comments.	

- b. Has this person or persons communicated to you or anyone on the ADP workgroup what they expect to be in the proposed rule (e.g., exemptions, requirements of the facilities)? If so, please explain what they expect to be in the proposed rule?

(b) (6), (b) (5)

- c. What is the anticipated date of publication of the proposed rule in the Federal Register?

(b) (5)

15. (b) (6), (b) (5)

#### Process to Reopen or Redo an RTR

16. Does OAQPS have a process to reopen or redo an RTR whenever there is new information, such as a new IRIS assessment, that call into question the protectiveness of existing NESHAP standards? If not, why?

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/13/19
No comments.	



(b) (5)

#### RTRs That Have Concluded Existing NESHAP Not Providing Ample Margin of Safety

17. We have not reviewed all RTRs that have ever been conducted, but the ones that we have looked at all conclude existing NESHAPs provide ample margin of safety to protect public health. Thus, no changes to existing NESHAPs are warranted. Do you know of any RTRs that concluded the existing NESHAP does not provide ample margin of safety to protect public health and therefore, the NESHAP is being revised? If so, which ones?

(b) (5)

#### Workgroup Membership

18. We heard that Regions 2 and 5 hosted ethylene oxide calls in the spring or summer of 2018. These regional-led ethylene oxide calls were then ended by OAQPS or HQ.
- a. Who decided to end these ethylene oxide calls? Why were they ended? (b) (6), (b) (5)
  - b. The regional-led ethylene oxide calls were then replaced with a chemical workgroup and a sterilizer workgroup in late August or early September 2018.
    - i. We heard that (b) (6) led the chemical workgroup. Were you in the chemical workgroup as well? (b) (6)

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/13/19
No comments.	

ii. If you were in the chemical workgroup, what issues were discussed in the chemical workgroup? (b) (6)

iii. Do you know what issues were discussed in the sterilizer workgroup? (b) (6)

19. **A** [Link](#): [Link](#): Do you have knowledge of the following HQ directives or heard of the following HQ directives in any sterilizer workgroup calls or anywhere else?

- Directive not to do inspections at ethylene oxide facilities. (b) (5)
- Directive not to do monitoring at ethylene oxide facilities. (b) (5)

- Directive not to do modeling at ethylene oxide facilities. (b) (5)
- Directive for Region 5 not to work with ATSDR. (b) (5)
- Directive not to release the May 2018 monitoring data at Sterigenics in June 2018. (b) (5)
- Directive not to send 114 letters to ethylene oxide facilities. (b) (6), (b) (5)

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/13/19
No comments.	

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.02.t**

**PURPOSE:** To interview (b)(6) regarding EPA's role in addressing ethylene oxide emissions.

**SCOPE:** Interviewed (b)(6) regarding EPA's role in addressing ethylene oxide emissions.

**SOURCE:** A) EPA OAR OAQPS, Residual Risk Assessment for the Hydrochloric Acid Production Source Category in Support of the 2018 Risk and Technology Review Proposed Rule, December 2018 (b)(6)

B) 5/13/19 response from (b)(6) regarding (b)(5)

C) Spreadsheet showing (b)(5)

(b)(6)

D) See the list of meeting participants below.

**DATE and TIME:** 5/7/19, 3:00 – 4:30 PM EDT.

**LOCATION:** (b)(6)

**PARTICIPANTS:**

(b)(6)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/13/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/14/19
No comments.	

OIG – Office of Audit and Evaluation – Air Directorate  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy points from the interview included:

- There are 19 facilities in the HCl production source category. (b) (6), (b) (5)

[REDACTED]

**DETAILS:**

After introductions, the following questions were asked. (b)(6) responses are in blue text.

Background on (b)(6)

1. What is your title or role in (b) (6)

(b)(6)

2. How long have you been in your current position?

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

(b) (6)

3. Who do you report to?

(b)(6)

#### RTR for HCl Production

4. Please provide a high-level overview of the risk assessment conducted for the RTR, including the results.

(b) (6), (b) (5)

[REDACTED]

[REDACTED]

There are 19 facilities in the HCl production source category. There are two HAPs (hazardous air pollutants, i.e., air toxics) – HCl and chlorine, (b) (5)

[REDACTED]

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

(b) (5)

You can read more about this in the executive summary section of the HCl production RTR risk assessment. (b) (6)  
[redacted] provided us with a copy of the risk assessment for the HCl production RTR proposed rule. See Source A.]

5. The February 4, 2019 proposed rule for the HCl production RTR stated that “the maximum facility-wide cancer Maximum Individual Risk (MIR) is 600 in one million, mainly driven by ethylene oxide emissions from a variety of industrial processes, none of which are part of this source category.” Of the 19 facilities that are subject to the NESHAP for HCl production, how many of them engage in processes that emit ethylene oxide?

(b) (6), (b) (5)

- a. How many of these ethylene oxide-emitting facilities are subject to the NESHAP for HON? (b) (6), (b) (5)
- b. How many of these ethylene oxide-emitting facilities are subject to the NESHAP for MON? (b) (6), (b) (5).
- c. How many of these ethylene oxide-emitting facilities are subject to the NESHAP for polyether polyols production? (b) (6), (b) (5)
- d. Could we get a list of the HCl production facilities that are engaged in processes that emit ethylene oxide? Yes (b) (6), (b) (5)  
[redacted]
- e. Are there any previous RTRs where the maximum facility-wide cancer MIR is 100 in one million or greater? If so, how did OAQPS address this risk to bring it down to below 100 in one million?

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

(b) (6), (b) (5)

6. The proposed rule for the HCl production RTR stated that “the EPA is interested in receiving public comments on the use of the update[d] risk value for regulator purposes.” This is in reference to the updated risk value for ethylene oxide issued by the IRIS program. Why was this statement included in the proposed rule?

(b) (6), (b) (5).

- a. Have there been any new scientific studies since December 2016 that suggest ethylene oxide is not as potent in cancer toxicity as the IRIS program had concluded? If so, please provide us with a list of the new scientific studies.

(b) (6), (b) (5).

- b. The statement suggests that EPA is open to using a lower risk value for ethylene oxide for regulatory purposes. (b) (6), (b) (5)

(b) (5)

- c. Did (b) (6) agree to include the statement in the proposed rule? Please explain.

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/13/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/14/19
No comments.	

(b) (5)

d. (b) (6), (b) (5)

e. Does OAQPS have the authority to use a risk value different than what the IRIS program issued for regulatory purposes?

(b) (5)

f. If someone from the public has reservations about an IRIS-issued risk value, isn't the appropriate recourse to file a Request for Correction (RFC) with the IRIS program under the Information Quality Act? If so, why did the proposed rule include the statement on collecting comments on the use of the IRIS-issued updated risk value for ethylene oxide?

(b) (5)

7. The proposed rule noted that EPA intends to evaluate those facility-wide estimated emissions and risks further and may address these in a separate future action, as appropriate.

a. Given that the estimated cancer MIR is 600 in one million, isn't it EPA's policy to take action because it's above the threshold of 100 in one million?

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/13/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/14/19
No comments.	



(b) (5)

- b. Are there any plans to reopen or redo the RTR for HON and RTR for polyether polyols production? If so, have ADP actions started for these RTRs?

(b) (5)

#### RTRs That Have Concluded Existing NESHAP Not Providing Ample Margin of Safety

8. We have not reviewed all RTRs that have ever been conducted, but the ones that we have looked at all conclude existing NESHAPs provide ample margin of safety to protect public health. Thus, no changes to existing NESHAPs are warranted. Do you know of any RTRs that concluded the existing NESHAP does not provide ample margin of safety to protect public health and therefore, the NESHAP is being revised? If so, which ones?

(b) (5)

9. How would OAQPS set standards to bring residual risk below 100 in one million if the technology is not available to bring the risk down? Would the standard be to limit facility operation (e.g., instead of operating 24 hours, facilities must not operate more than 12 hours per day)?

(b) (5)

#### Comments on the Proposed Rule

10. We understand that comments on the proposed rule for the HCl production RTR were due on March 21, 2019.

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

- a. Were there any comments regarding the use of a lower risk value for ethylene oxide for regulatory purposes? If so, were the majority of the comments in favor of retaining the updated IRIS-issued risk value for ethylene oxide?

(b) (5)

- b. Does OAQPS intend to use a different risk value for ethylene oxide in future regulations?

(b) (5)

11. Where in the ADP process is the action at right now?

(b) (5)

- a. When will the final rule be issued? Will it meet the court-ordered deadline of March 13, 2020?

(b) (5)

- b. Will the final rule include the issuance of a new risk value for ethylene oxide for future regulations?

(b) (5) (b) (5)

#### Directives

12. Do you have knowledge of the following HQ directives or heard of the following HQ directives in any sterilizer workgroup calls or anywhere else?

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/13/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/14/19
No comments.	

- Directive not to do inspections at ethylene oxide facilities. (b) (6), (b) (5)
- Directive not to do monitoring at ethylene oxide facilities. (b) (6), (b) (5)
- Directive not to do modeling at ethylene oxide facilities. (b) (6), (b) (5)
- Directive for Region 5 not to work with ATSDR. (b) (6), (b) (5)
- Directive not to release the May 2018 monitoring data at Sterigenics in June 2018. (b) (6), (b) (5)
- Directive not to send 114 letters to ethylene oxide facilities. (b) (6), (b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/13/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/14/19
No comments.	

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.02.u**

**PURPOSE:** To interview (b)(6) regarding EPA's role in addressing ethylene oxide emissions.

**SCOPE:** Interviewed (b)(6) regarding EPA's role in addressing ethylene oxide emissions.

**SOURCE:** A) See the list of meeting participants below.

**DATE and TIME:** 5/8/19, 9:00 – 10:30 AM EDT.

**LOCATION:** (b) (6)

**PARTICIPANTS:**

(b)(6)

**OIG – Office of Audit and Evaluation – Air Directorate**  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy points from the interview included:

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

- (b) (5), (b) (6)
- (b) (6)

**DETAILS:**

After introductions, the following questions were asked. (b)(6) responses are in blue text.

Background on (b)(6)

1. What is your title or role in (b) (6)

(b)(6)

2. How long have you been in your current position?

(b)(6)

(b)(6)

3. Who do you report to?

(b) (6)

RTR for HCl Production

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

4. Do you normally review all proposed and final rules that are issued by your division?

(b) (6), (b) (5)

5. Did you review the draft proposed rule for the HCl production RTR as it was moving along the ADP process? If so, at what points did you review the draft proposed rule?

(b) (5), (b) (6)

6. The February 4, 2019 proposed rule for the HCl production RTR stated that “the EPA is interested in receiving public comments on the use of the update[d] risk value for regulatory purposes.” This is in reference to the updated risk value for ethylene oxide issued by the IRIS program. Why was this statement included in the proposed rule?

(b) (5)

a. Have there been any new scientific studies since December 2016 that suggest ethylene oxide is not as potent in cancer toxicity as the IRIS program had concluded? If so, please provide us with a list of the new scientific studies.

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

(b) (5)

- b. The statement suggests that EPA is open to using a lower risk value for ethylene oxide for regulatory purposes. (b) (6)  
If so, what is the reasoning for including the statement in the proposed rule?

(b) (5)

- c. Do you believe that a lower risk value for ethylene oxide for regulatory purposes should be used? If so, what risk value should be used? And what is your support for the lower risk value?

(b) (5)

- d. Does OAQPS have the authority to use a risk value different than what the IRIS program issued for regulatory purposes?

(b) (5)

- e. If someone from the public has reservations about an IRIS-issued risk value, isn't the appropriate recourse to file a Request for Correction (RFC) with the IRIS program under the Information Quality Act? If so, why did the proposed rule include the statement on collecting comments on the use of the IRIS-issued updated risk value for ethylene oxide.

(b) (5)

- f. Have there been any instances in the last three years where upper management or senior leadership instructed ADP workgroups to include statements in proposed or final rules that are not supported by the best available science? If so, please explain.

(b) (6), (b) (5)

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

(b) (5)

7. The proposed rule stated that “the maximum facility-wide cancer Maximum Individual Risk (MIR) is 600 in one million, mainly driven by ethylene oxide emissions from a variety of industrial processes, none of which are part of this source category.” The proposed rule also noted that EPA intends to evaluate the facility-wide estimated emissions and risks further and may address these in a separate future action, as appropriate.

- a. Given that the estimated cancer MIR is 600 in one million, isn't it EPA's policy to take action because it's above the threshold of 100 in one million?

(b) (5)

- b. Are there any plans to reopen or redo the RTR for HON and RTR for polyether polyols production? If so, have ADP actions started for these RTRs?

(b) (5)

(b) (6)

(b) (5)

#### Process to Reopen or Redo an RTR

8. Are there any previous RTRs where the maximum facility-wide cancer MIR is 100 in one million or greater? If so, how did OAQPS address this risk to bring it down to below 100 in one million?

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	



(b) (6), (b) (5)

9. Does OAQPS have a process to reopen or redo an RTR that is driving the maximum facility-wide cancer MIR above 100 in one million?

(b) (5)

10. Does OAQPS have a process to reopen or redo an RTR whenever there is new information, such as a new IRIS assessment, that call into question the protectiveness of existing NESHAP standards?

(b) (5)

#### RTRs That Have Concluded Existing NESHAP Not Providing Ample Margin of Safety

11. We have not reviewed all RTRs that have ever been conducted, but the ones that we have looked at all conclude existing NESHAPs provide ample margin of safety to protect public health. Thus, no changes to existing NESHAPs are warranted. Do you know of any RTRs that concluded the existing NESHAP does not provide ample margin of safety to protect public health and therefore, the NESHAP is being revised? If so, which ones?

(b) (6), (b) (5)

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

12. How would OAQPS set standards to bring residual risk below 100 in one million if the technology is not available to bring the risk down? Would the standard be to limit facility operation (e.g., instead of operating 24 hours per day, facilities must not operate more than 12 hours per day)?

I'm not the expert on that.

#### RTRs for MON and Commercial Sterilizers

13. We understand that the RTRs for MON and commercial sterilizers are currently being conducted and the proposed rules are expected to be issued in the summer.

- a. Are you reviewing the draft proposed rules?

(b) (6), (b) (5)



Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

(b) (5)

b. How involved is senior leadership in these two upcoming proposed rules?

(b) (5)

#### Directives

14. Do you have knowledge of the following HQ directives or heard of the following HQ directives?

- Directive not to do inspections at ethylene oxide facilities. (b) (6), (b) (5)
- Directive not to do monitoring at ethylene oxide facilities. (b) (6), (b) (5)
- Directive not to do modeling at ethylene oxide facilities. (b) (6), (b) (5)
- Directive for Region 5 not to work with ATSDR. (b) (6), (b) (5)
- Directive not to release the May 2018 monitoring data at Sterigenics in June 2018. (b) (6), (b) (5)
- Directive not to send 114 letters to ethylene oxide facilities. (b) (6), (b) (5)

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.02.v**

**PURPOSE:** To interview (b)(6) regarding EPA's role in addressing ethylene oxide emissions.

**SCOPE:** Interviewed (b)(6) regarding EPA's role in addressing ethylene oxide emissions.

**SOURCE:** A) See the list of meeting participants below.

**DATE and TIME:** 5/8/19, 10:30 AM – 12:00 PM EDT.

**LOCATION:** (b) (6)

**PARTICIPANTS:**

(b)(6)

**OIG – Office of Audit and Evaluation – Air Directorate**  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy points from the interview included:

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/13/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/14/19
No comments.	

- (b) (5), (b) (6) [redacted]  
[redacted]  
[redacted]

**DETAILS:**

After introductions, the following questions were asked. (b)(6) responses are in blue text.

Background on (b)(6) [redacted]

1. What is your title or role in (b) (6)

(b)(6) [redacted]

2. How long have you been in your current position?

(b) (6) [redacted]

3. Who do you report to?

(b)(6) [redacted]

**Assistance to Region 5**

4. We heard that you (b) (6), (b) (5) [redacted].

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/13/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/14/19
No comments.	

a. (b) (6), (b) (5)

[REDACTED]

[REDACTED]

(b) (6), (b) (5)  
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

b. (b) (6)

#### **Sending CAA Section 114 Letters to Facilities**

5. We have heard that Region 5 (b) (6), (b) (5)

(b) (5)

#### **Assistance to Other Regions or States**

6. (b) (6) provided any assistance to other regions or states regarding ethylene oxide facilities? If so, please explain.

(b) (6), (b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/13/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/14/19
No comments.	

(b) (5), (b) (6)

(b) (5), (b) (5), (b) (6)

(b) (5), (b) (5), (b) (6)

(b) (5), (b) (5), (b) (6)

(b) (6)

7. (b) (6), (b) (5)

- a. Have you been in any workgroups (e.g., regional-led ethylene oxide calls in spring/summer of 2018, chemical or sterilizer workgroup, rulemaking workgroups)?

(b) (5), (b) (6)

(b) (6)

(b) (6), (b) (5)

- b. In the workgroups that you have been involved with, has the two-pronged approach come up? If so, in what context?

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	



(b) (6), (b) (5)

- c. In any of the workgroup calls or anywhere else, did any of the following directives come up? If so, please elaborate.
- Directive not to do inspections at ethylene oxide facilities.

(b) (6), (b) (5)

- Directive not to do monitoring at ethylene oxide facilities.

(b) (6), (b) (5)

- Directive not to do modeling of ethylene oxide facilities.

(b) (6), (b) (5) .

- Directive for Region 5 not to work with ATSDR.

(b) (6), (b) (5) .

- Not to send 114 letters.

(b) (6), (b) (5)

- Directive not to release the May 2018 monitoring data at Sterigenics in June 2018.

(b) (6), (b) (5)

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

## Ambient Monitoring of Ethylene Oxide

8. Although Region 5 and OAQPS have conducted ambient monitoring of Sterigenics in Willowbrook, Illinois, we have heard that (b) (5)

(b) (5)

9. Given the results of the ambient monitoring of Sterigenics, do you see value in conducting ambient monitoring of ethylene oxide despite the current detection limit? Why or why not?

(b) (5)

(b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/13/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/14/19
No comments.	

10. The 4.5 months of ambient monitoring conducted between November 2018 and March 2019 at Sterigenics showed that ethylene oxide concentrations were generally higher than before the back vent emissions were controlled. What do you think is the reason for the higher than expected ambient concentrations?

(b) (5)

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.02.w**

**PURPOSE:** To interview (b)(6) regarding EPA's role in addressing ethylene oxide emissions.

**SCOPE:** Interviewed (b)(6) regarding EPA's role in addressing ethylene oxide emissions.

**SOURCE:** A) 9/20/18 ACC submission of RFC to EPA regarding risk value used for ethylene oxide in the 2014 NATA  
(<https://www.americanchemistry.com/EO/Request-for-Correction-under-the-Information-Quality-Act-2014-NATA.pdf>, accessed 6/6/19)

B) See the list of meeting participants below.

**DATE and TIME:** 5/8/19, 2:00 – 3:00 PM EDT.

**LOCATION:** (b) (6)

**PARTICIPANTS:**

(b)(6)

**OIG – Office of Audit and Evaluation – Air Directorate**  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one meeting.

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

**SUMMARY:** Noteworthy points from the interview included:

- (b) (6), (b) (5) [REDACTED]

**DETAILS:**

After introductions, the following questions were asked. (b) (5), (b) (6) responses are in blue text.

Background on (b)(6) [REDACTED]

1. What is your title or role in (b) (6) [REDACTED]

(b)(6) [REDACTED]

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

2. How long have you been in your current position?

(b)(6)

3. Who do you report to?

(b)(6)

**RTR for HCl Production**

4. (b) (6) ?

(b)(6)

5. Did you review the draft proposed rule for the HCl production RTR as it was moving along the ADP process? If so, at what points did you review the draft proposed rule?

(b) (5), (b) (6)

6. The February 4, 2019 proposed rule for the HCl production RTR stated that "the EPA is interested in receiving public comments on the use of the update[d] risk value for regulator purposes." This is in reference to the updated risk value for ethylene oxide issued by the IRIS program. Why was this statement included in the proposed rule?

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

(b) (5)

(b) (5)

- a. Have there been any new scientific studies since December 2016 that suggest ethylene oxide is not as potent in cancer toxicity as the IRIS program had concluded? If so, please provide us with a list of the new scientific studies.

(b) (5)

- b. The statement suggests that EPA is open to using a lower risk value for ethylene oxide for regulatory purposes. Did you or senior leadership instruct the ADP workgroup to include the statement in the proposed rule? If so, what is the reasoning for including the statement in the proposed rule?

(b) (5)

- c. Do you believe that a lower risk value for ethylene oxide for regulatory purposes should be used? If so, what risk value should be used? And what is your support for the lower risk value?

(b) (5)

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

(b) (5)

- d. Does OAQPS have the authority to use a risk value different than what the IRIS program issued for regulatory purposes?

(b) (5)

- e. If someone from the public has reservations about an IRIS-issued risk value, isn't the appropriate recourse to file a Request for Correction (RFC) with the IRIS program under the Information Quality Act? If so, why did the proposed rule include the statement on collecting comments on the use of the IRIS-issued updated risk value for ethylene oxide.

(b) (5)

[Evaluator note: On 9/18/18, (b) (5)

. See Source A.]

(b) (5)

- f. Have there been any instances in the last three years where upper management or senior leadership instructed ADP workgroups to include statements in proposed or final rules that are not supported by the best available science? If so, please explain.

(b) (5)

7. The proposed rule stated that "the maximum facility-wide cancer Maximum Individual Risk (MIR) is 600 in one million, mainly driven by ethylene oxide emissions from a variety of industrial processes, none of which are part of this source category." The proposed rule also noted that EPA intends to evaluate the facility-wide estimated emissions and risks further and may address these in a separate future action, as appropriate.

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	



- a. Given that the estimated cancer MIR is 600 in one million, isn't it EPA's policy to take action because it's above the threshold of 100 in one million?

(b) (5)

- b. Are there any plans to reopen or redo the RTR for HON and RTR for polyether polyols production? If so, have ADP actions started for these RTRs?

(b) (5)

#### Process to Reopen or Redo an RTR

8. Are there any previous RTRs where the maximum facility-wide cancer MIR is 100 in one million or greater? If so, how did OAQPS address this risk to bring it down to below 100 in one million?

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

(b) (5)

9. Does OAQPS have a process to reopen or redo an RTR that is driving the maximum facility-wide cancer MIR above 100 in one million?

(b) (5)

10. Does OAQPS have a process to reopen or redo an RTR whenever there is new information, such as a new IRIS assessment, that call into question the protectiveness of existing NESHAP standards?

(b) (5)

#### RTRs That Have Concluded Existing NESHAP Not Providing Ample Margin of Safety

11. We have not reviewed all RTRs that have ever been conducted, but the ones that we have looked at all conclude existing NESHAPs provide ample margin of safety to protect public health. Thus, no changes to existing NESHAPs are warranted. Do you know of any RTRs that concluded the existing NESHAP does not provide ample margin of safety to protect public health and therefore, the NESHAP is being revised? If so, which ones?

(b) (5)

#### RTRs for MON and Commercial Sterilizers

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

12. (b) (5)

(b) (5)

(b) (5)

(b) (5)


13. Do you have knowledge of the following HQ directives or heard of the following HQ directives?

- Directive not to do inspections at ethylene oxide facilities. (b) (6), (b) (5)
- Directive not to do monitoring at ethylene oxide facilities. (b) (6), (b) (5)
- Directive not to do modeling at ethylene oxide facilities. (b) (6), (b) (5)
- Directive for Region 5 not to work with ATSDR. (b) (6), (b) (5)
- Directive not to release the May 2018 monitoring data at Sterigenics in June 2018. (b) (6), (b) (5)
- Directive not to send 114 letters to ethylene oxide facilities. (b) (6), (b) (5)

(b) (5)

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

(b) (5)



Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources  
OA&E-FY19-0091  
WP H.02.x**

**PURPOSE:** To interview (b)(6) regarding EPA's role in addressing ethylene oxide emissions.

**SCOPE:** Interviewed (b)(6) regarding EPA's role in addressing ethylene oxide emissions.

**SOURCE:** A) Calendar of events that were to occur since the 2014 NATA was QA/QC'd.

B) See the list of meeting participants below.

**DATE and TIME:** 5/8/19, 3:15 – 4:45 PM EDT.

**LOCATION:** (b) (6)

**PARTICIPANTS:**

**Link:** (b)(6)

OIG – Office of Audit and Evaluation – Air Directorate  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy points from the interview included:

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/13/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/14/19
No comments.	

- (b) (5), (b) (6)

**DETAILS:**

After introductions, the following questions were asked. (b)(6) responses are in blue text.

Background on (b)(6)

1. What is your title or role in (b) (6)

(b)(6)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/13/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/14/19
No comments.	

2. How long have you been in your current position?

(b) (6)

3. Who do you report to?

(b)(6)

4. How are you currently involved with EPA's efforts to address ethylene oxide emissions?

(b) (5), (b) (6)

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

## Workgroup Membership

5. We heard that Regions 2 and 5 hosted ethylene oxide calls in the spring or summer of 2018. These regional-led ethylene oxide calls were then stopped by OAQPS or HQ.

- a. Who decided to end the ethylene oxide calls? Why was that decision made?

(b) (5)

- b. The regional-led ethylene oxide calls were then replaced with a chemical workgroup and a sterilizer workgroup in late August or early September 2018.

- i. Were you in these two workgroups? (b) (6)

- ii. What issues were discussed in the two workgroups?

(b) (5)

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	



- c. We heard that the chemical and sterilizer workgroups stopped meeting in late February or early March 2019 and replaced with ethylene oxide coordination calls.

(b) (6), (b) (5)

- i. Have you been participating in the ethylene oxide coordination calls?

(b) (6)

- ii. What issues are discussed in the ethylene oxide coordination calls?

(b) (5)

- iii. Why did the workgroups stop meeting?

(b) (5)

#### List of 25 Facilities that Contribute to Elevated Cancer Risks

6. We heard that OAQPS distributed a list of 25 facilities that contributed to elevated cancer risks to the regions for them to focus on.

- a. Is that correct?

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

(b) (5)

Link: (b) (5)

(b) (5)

- b. What is OAQPS or HQ's expectations of the regions with respect to these 25 facilities? Were these expectations written and sent to the regions?

Link: [WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docx](#) (b) (5)

(b) (5)

- c. What milestones were associated with these expectations?

Link: [WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docx](#) (b) (5)

7. Did the initial list contain more than 25 facilities? If so, what criteria was used to get the list down to 25?

(b) (5)

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

8. We understand that one of the criteria for facilities to get listed was if they contributed to a cancer risk of  $\geq 100$  in one million at the census tract level. They can also be listed if they contributed to a cancer risk of  $\geq 1,000$  in one million at the census block level. Is this correct?

(b)(6)

9. We understand that it has been a long-standing EPA policy that a risk of 100 in 1,000,000 does not provide an ample margin of safety to protect public health. Why was a cancer risk of  $\geq 1,000$  in one million at the census block level selected?

(b) (5)

10. During the kickoff meeting, you mentioned that there are 19 Metropolitan Statistical Areas (MSAs) that have elevated cancer risks. Are all 25 of these facilities within the 19 MSAs?

(b) (5)

11. Has EPA informed the public and elected officials in the 19 MSAs of the elevated cancer risks? If not, why not?

(b) (5) (b) (5)

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

(b) (5)

[Evaluator note: On 6/6/19, (b)(6) provided us with the calendar of events. See Source A. The following acronyms were used in Source A:

ADD = Air Division Directors

AQAD = Air Quality Assessment Division

EtO = ethylene oxide

GLs = Group Leaders

HEID = Health and Environmental Impacts Division

NATA = National Air Toxics Assessment

NCEA = National Center for Environmental Assessment

OAQPS = Office of Air Quality Planning and Standards

OAR = Office of Air and Radiation

OD = Office of the Director

ORD = Office of Research and Development

OTAQ = Office of Transportation and Air Quality

PADs = Public Affairs Directors

TSD = Technical Support Document]

(b) (5)

12. Do inspections and enforcement come into play in the two-pronged strategy to address ethylene oxide emissions?

(b) (5)

13. We had heard that Region 5 was directed not to conduct inspections unless they were invited by a state to conduct a joint inspection.

a. Are you aware of this directive? (b) (6)

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

b. Was the same directive issued to other regions? (b) (5)

14. How is EPA going to address the (b) (5) ?

(b) (5)

#### Directive Not to Send CAA Section 114 Letters to Facilities

15. We understand that the second prong of the two-pronged approach to address ethylene oxide emissions involves gathering information. However, we learned that Region 5 staff were told not to issue Section 114 letters to ethylene oxide facilities.

a. Are you aware of this directive?

(b) (5)

(b) (5)

b. Who issued the directive?

[See response to Question 15a.](#)

c. Was the same directive issued to other regions?

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

(b) (5)

#### Directive to Get Permission from OAQPS to Conduct Modeling

16. We heard that Region 5 was told to seek permission from OAQPS before conducting any modeling of ethylene oxide facilities.

a. Are you aware of this directive?

(b) (5)

b. Who instructed Region 5 to get permission from OAQPS to conduct modeling?

(b) (5)

c. Why was this instruction given to Region 5?

[See response to Question 16a.](#)

d. Was the same instruction given to other regions?

(b) (5)

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

## Directive Not to Conduct Monitoring

17. **A** [Link: Link](#): We understand that OAQPS recently completed ambient monitoring of Sterigenics in Willowbrook. We also heard that the agency won't be conducting monitoring of ethylene oxide emissions from other facilities.

a. Who made the decision that EPA won't be conducting monitoring of ethylene oxide emissions from other facilities?

(b) (5)

b. What was the reasoning behind this decision?

(b) (5)

## OAQPS Now the Contact Point for Sterigenics

18. We heard that (b) (5)

(b) (5)

a. Why has OAQPS taken over communication with these facilities?

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

(b) (5)

b. Has OAQPS taken over communication with other facilities in other regions as well?

(b) (5)

#### 2014 NATA

19. When was the QA/QC of the 2014 NATA completed? When was the 2014 NATA ready to be released to the public?

(b) (5)

20. Did senior leadership or anyone in upper management prefer that the 2014 NATA be released later than August 2018? If so, when was the preferred release date and why?

(b) (5)

#### 2017 NATA

21. When did development of the 2017 NATA start?

(b) (5)

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	



22. When will EPA send out the 2017 NATA data to the states for data confirmation?

(b) (5)

23. What is the anticipated release date of the 2017 NATA?

(b) (5)

24. Has the 2017 NATA been scaled back in any way? If so, please explain.

(b) (5)

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.02.y**

**PURPOSE:** To interview (b)(6) regarding EPA's role in addressing ethylene oxide emissions.

**SCOPE:** Interviewed (b)(6) regarding EPA's role in addressing ethylene oxide emissions.

**SOURCE:** A) See the list of meeting participants below.

**DATE and TIME:** 5/9/19, 10:00 – 11:30 AM EDT.

**LOCATION:** (b) (6)

**PARTICIPANTS:**

[Link:](#) (b)(6)

**OIG – Office of Audit and Evaluation – Air Directorate**  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy points from the interview included:

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/13/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/14/19
No comments.	

- (b) (5), (b) (6)

**DETAILS:**

After introductions, the following questions were asked. (b)(6) responses are in blue text.

Background on (b)(6)

1. What is your title or role in (b) (6)

(b)(6)

2. How long have you been in your current position?

(b) (6) .

3. Who do you report to?

(b)(6)

4. How are you currently involved with EPA's efforts to address ethylene oxide emissions? (e.g., Are you on the ethylene oxide coordination calls?)

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

(b) (6), (b) (5)

(b) (5)

(b) (5)

We met with the Willowbrook community back in

November 2018. You can watch that meeting on YouTube. (b) (5)

(b) (5)

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

(b) (5)

#### List of 25 Facilities that Contribute to Elevated Cancer Risks

5. We heard that OAQPS distributed a list of 25 facilities that contributed to elevated cancer risks to the regions for them to focus on.

a. Is this correct? If so, how were those 25 facilities identified?

Link: (b) (5)

b. What is OAQPS or HQ's expectations of the regions with respect to these 25 facilities?

Link: WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docx (b) (5)

This question is probably best for (b) (6) . (b) (5)

Link: WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docx

c. What milestones were associated with these expectations? Ask (b) (6)

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

6. Did the initial list contain more than 25 facilities? If so, what criteria was used to get down to 25 facilities?

(b)(6)

7. We understand that one of the criteria for facilities to get listed was if they contributed to a cancer risk of  $\geq 100$  in one million at the census tract level. They can also be listed if they contributed to a cancer risk of  $\geq 1,000$  in one million at the census block level. Is this correct? You should talk to (b) (6).

a. We understand that it has been a long-standing EPA policy that a risk of 100 in 1,000,000 does not provide an ample margin of safety to protect public health. Why was a cancer risk of  $\geq 1,000$  in one million at the census block level selected? You should talk to (b) (6).

8. During the kickoff meeting, you mentioned that there are 19 Metropolitan Statistical Areas (MSAs) that have elevated cancer risks. Are all 25 of these facilities within the 19 MSAs? That would be a (b) (6) question.

9. Has EPA informed the public and elected officials in the 19 MSAs of the elevated cancer risks? If not, why not? That would be a (b) (6) question. (b) (5)

#### Directive Not to Conduct Inspections or Take Enforcement Actions

10. Do inspections and enforcement come into play in the two-pronged strategy to address ethylene oxide emissions? (b) (5), (b) (6)

11. We had heard that Region 5 was directed not to conduct inspections unless they were invited by a state to conduct a joint inspection.

a. Are you aware of such a directive? (b) (5).

b. Was the same directive issued to other regions? (b) (5).

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

12. We heard that (b) (5)

#### Directive Not to Send CAA Section 114 Letters to Facilities

13. We understand that the second prong of the two-pronged approach to address ethylene oxide emissions involves gathering information. However, we learned that Region 5 staff were told not to issue Section 114 letters to ethylene oxide facilities.

a. Are you aware of such a directive? (b) (5)

#### Directive to Get Permission from OAQPS to Conduct Modeling

14. We heard that Region 5 was told to seek permission from OAQPS before conducting any modeling on ethylene oxide facilities.

a. Are you aware of such a directive? (b) (5)

#### Directive Not to Conduct Monitoring

15. We understand that OAQPS recently completed ambient monitoring of Sterigenics in Willowbrook. We also heard that the agency won't be conducting monitoring of ethylene oxide emissions from other facilities.

a. Are you aware of such a directive? (b) (5)

b. Who made the decision that EPA won't be conducting monitoring of ethylene oxide emissions from other facilities? (b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/13/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/14/19
No comments.	

c. What was the reasoning behind this decision? (b) (5)

[REDACTED]

#### OAQPS Now the Contact Point for Sterigenics

16. (b) (5)

[REDACTED]

(b) (5)

[REDACTED]

[REDACTED]

[REDACTED]

a. Why has OAQPS taken over communication with these facilities? (b) (5)

[REDACTED]

b. Has OAQPS taken over communication with other facilities in other regions as well? (b) (5)

[REDACTED]

#### 2014 NATA

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/13/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/14/19
No comments.	



17. When was the QA/QC of the 2014 NATA completed? (b) (5)

18. Did senior leadership or anyone in upper management prefer that the 2014 NATA be released later than August 2018? If so, when was the preferred release date and why? (b) (5)

2017 NATA

19. When did development of the 2017 NATA start? (b) (5)

20. Has the 2017 NATA been scaled back in any way? If so, please explain. (b) (5)

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

(b) (5)

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.02.z**

**PURPOSE:** To interview (b)(6) regarding EPA's role in addressing ethylene oxide emissions.

**SCOPE:** Interviewed (b)(6) regarding EPA's role in addressing ethylene oxide emissions.

**SOURCE:** A) Excel spreadsheet of (b) (5) (b) (6)  
[REDACTED]. Spreadsheet is deliberative – not to be released under FOIA.)

B) 5/17/19 email from (b)(6) containing notes about Source A Excel spreadsheet.

C) See the list of meeting participants below.

**DATE and TIME:** 5/9/19, 2:00 – 3:00 PM EDT.

**LOCATION:** (b) (6)

**PARTICIPANTS:**

(b)(6)  
[REDACTED]

OIG – Office of Audit and Evaluation – Air Directorate  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy points from the interview included:

- (b) (5), (b) (6)

**DETAILS:**

After introductions, the following questions were asked. (b) (6) responses are in blue text.

Background on (b)(6)

1. What is your title or role in (b) (6)

(b)(6)

2. How long have you been in your current position?

(b)(6)

3. Who do you report to?

(b)(6)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/13/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/14/19
No comments.	

## Involvement with NATA

4. What is your role in the development of the 2014 NATA?

(b) (6)

5. Were you involved with previous NATAs as well?

(b)(6)

6. Are you involved with development of the 2017 NATA?

(b) (5)

[Evaluator note: We asked (b)(6) for the

(b) (6), (b) (5)

. (Source B)]

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	

7. Where in the process is the 2017 NATA development?

[See response to Question 6.](#)

8. Are there any changes between the 2014 and 2017 NATA developments?

(b) (5)

- a. Will the 2017 NATA be scaled back in any way? (e.g., number of pollutants to be analyzed, number of risk values to be calculated)

(b) (5)

- b. Will there be any improvements to the development process to improve accuracy? If so, please explain.

(b) (5)

#### Emissions Data Used for NATA

9. Please describe the emissions data used for the 2014 NATA development. (e.g., strictly NEI, combination of NEI and TRI or other data)

(b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/13/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/14/19
No comments.	

10. Please describe the process used to ensure accuracy of the emissions data that go into the risk assessment for NATA.

(b) (5)

(b) (5)

(b) (5)

11. (b) (5)

(b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/13/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/14/19
No comments.	

(b) (5)

12. What controls will be in place to ensure that something similar to what happened with Vantage Specialty Chemicals does not happen in future NATA developments?

(b) (5)

#### Workgroup Involvement

13. Have you been involved in any workgroups to address ethylene oxide emissions (e.g., regional-led ethylene oxide calls in spring/summer of 2018, chemical or sterilizer workgroup, rulemaking workgroups)? (b) (5)

a. In any of the workgroup calls or anywhere else, did any of the following directives come up? If so, please elaborate.

- Directive not to send 114 letters to ethylene oxide-emitting facilities. (b) (6), (b) (5)
- Directive not to do inspections at ethylene oxide facilities. (b) (5), (b) (6)
- Directive not to do monitoring at ethylene oxide facilities. (b) (5), (b) (6)
- Directive not to do modeling at ethylene oxide facilities. (b) (6), (b) (5)
- Directive for Region 5 not to work with ATSDR. (b) (6), (b) (5)
- Directive not to release the May 2018 monitoring data at Sterigenics in June 2018. (b) (6), (b) (5)

Prepared by:	Date
Bao Chuong	6/13/19
Approved by:	Date
Renee McGhee-Lenart	6/14/19
No comments.	



**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.02.q**

**PURPOSE:** To interview (b)(6) regarding EPA's role in addressing ethylene oxide emissions.

**SCOPE:** Interviewed (b)(6) regarding EPA's role in addressing ethylene oxide emissions.

**SOURCE:** A) ADP tracker for the upcoming commercial sterilizers proposed rule. (b) (6)

B) 5/7/19 email from (b)(6) confirming the list of ADP workgroup members.

C) See the list of meeting participants below.

**DATE and TIME:** 5/7/19, 9:00 – 10:30 AM EDT.

**LOCATION:** (b) (6)

**PARTICIPANTS:**

(b)(6)

**OIG – Office of Audit and Evaluation – Air Directorate**  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one meeting.

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/11/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/12/19
No comments.	

**SUMMARY:** Noteworthy points from the interview included:

- (b) (6), (b) (5) [REDACTED]
- [REDACTED]
- [REDACTED]

**DETAILS:**

After introductions, the following questions were asked. (b)(6) responses are in blue text.

Background on (b)(6)

1. What is your title or role in (b) (6)

(b)(6)

2. How long have you been in your current position?

(b) (6) .

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
No comments.	

3. Who do you report to?

(b)(6)

Upcoming Proposed Rule for (b) (5)

4. Please provide an overview of how the upcoming proposed rule came about. For example,

(b) (5) NATA is conducted every 4 years or so. NATA is a combined risk from all emission sources for the different census tracts. The IRIS value for ethylene oxide was updated in December 2016. (b) (5)

a. When did the Action Development Process (ADP) begin for the upcoming proposed rule?

(b) (5)

b. (b) (6)

(b) (5)

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
No comments.	

(b) (5)

c. (b) (6) ?

(b) (6), (b) (5)

5. What is the current tier of the ADP action?

(b) (5)

a. What is the reason for the current tier?

(b) (5)

b. Did anyone in the ADP workgroup propose to up tier the action?

(b) (5)

i. If so, what was the outcome of the up tier proposal?

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
No comments.	

(b) (5)

6. Is the upcoming proposed rule (b) (5)

?

(b) (5)

7. What data or information have you or the ADP workgroup collected to inform your rule proposal?

(b) (5)

a. Did you reach out to facilities for data or information?

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
No comments.	

(b) (5)

i. If so, how did you reach out to the facilities? [See response to Question 7a.ii.](#)

ii. Did you have to send out CAA Section 114 letters to facilities?

(b) (5), (b) (6)

b. What other stakeholders did (b) (6) reach out to? (e.g., Ethylene Oxide Sterilization Association, environmental advocacy groups)

(b) (5)

i. If so, what information did you ask from them? [See response to 7b.](#)

8. Please provide an overview of the new controls, work practices, or other standards that will be proposed in the upcoming rule.

(b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/11/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/12/19
No comments.	

(b) (5)

a. (b) (5)

?

(b) (5)

9. Where in the ADP process is the action at right now?

(b) (5)

a. Who in EPA will sign off on the upcoming proposed rule?

(b) (5)

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
No comments.	

- b. Has this person or persons communicated to you or anyone on the ADP workgroup what they expect to be in the proposed rule? If so, please explain what they expect to be in the proposed rule?

(b) (5)

- c. What is the anticipated date of publication of the proposed rule in the Federal Register?

(b) (5)

10. Will whether (b) (5) be addressed in the upcoming proposed rule?

(b) (5)

- a. If so, (b) (5) ? See response above.
- b. If not, why not? Not applicable. See response above.

11. Are there any plans to (b) (5) ?

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
No comments.	



(b) (5)

a. If so, has an ADP workgroup started? (b) (5).

b. If not, why not? Not applicable. See response above.

#### Process to Reopen or Redo an RTR

12. Does OAQPS have a process to reopen or redo an RTR whenever there is new information, such as a new IRIS assessment, that call into question the protectiveness of existing NESHAP standards?

(b) (5)

#### RTRs That Have Concluded Existing NESHAP Not Providing Ample Margin of Safety

13. We have not reviewed all RTRs that have ever been conducted, but the ones that we have looked at all conclude existing NESHAPs provide ample margin of safety to protect public health. Thus, no changes to existing NESHAPs are warranted. Do you know of any RTRs that concluded the existing NESHAP does not provide ample margin of safety to protect public health and therefore, the NESHAP is being revised? If so, which ones?

(b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/11/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/12/19
No comments.	

(b) (5)

#### Workgroup Membership

14. We heard that Regions 2 and 5 hosted ethylene oxide calls in the spring or summer of 2018. These regional-led ethylene oxide calls were then stopped by OAQPS or HQ.

a. Who requested that the ethylene oxide calls be stopped? What was the reasoning behind the decision?

(b) (5)

b. The regional-led ethylene oxide calls were then replaced with a chemical workgroup and a sterilizer workgroup in late August or early September 2018. (b) (6)

i. (b) (6)

ii. What issues were discussed in the sterilizer workgroup? (b) (5)

iii. During the sterilizer workgroup calls, was the two-pronged approach to address ethylene oxide emissions discussed? (b) (5)

iv. Do you know what issues were discussed in the chemical workgroup? (b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	6/11/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	6/12/19
No comments.	

c. We heard that the chemical and sterilizer workgroups stopped meeting in late February or early March 2019 and were replaced with ethylene oxide coordination calls.

i. Who decided that the chemical and sterilizer workgroups should stop meeting? Why were the two workgroups terminated?

(b) (5)

ii. Are you on the ethylene oxide coordination calls? If so, what issues are discussed in those calls?

(b) (5)

15. Do you have knowledge of the following HQ directives or heard of the following HQ directives in any sterilizer workgroup calls or anywhere else?

- Directive not to do inspections at ethylene oxide facilities.

(b) (5)

- Directive not to do monitoring at ethylene oxide facilities.

(b) (5)

- Directive not to do modeling at ethylene oxide facilities.

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
No comments.	

(b) (5)

- Directive for Region 5 not to work with ATSDR.

(b) (5)

- Directive not to release the May 2018 monitoring data at Sterigenics in June 2018.

(b) (5)

- Directive not to send 114 letters to ethylene oxide facilities.

(b) (5)

Prepared by:	Date
Bao Chuong	6/11/19
Approved by:	Date
Renee McGhee-Lenart	6/12/19
No comments.	

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.03.a**

**PURPOSE:** To meet with (b)(6) regarding Region 5's role in addressing ethylene oxide emissions.

**SCOPE:** Interviewed (b)(6) regarding Region 5's role in addressing ethylene oxide emissions.

**SOURCE:** A) Email from (b)(6) showing (b) (6), (b) (5)

B) See the list of meeting participants below.

**DATE and TIME:** 4/3/19, 1:00 – 2:30 PM CDT.

**LOCATION:** (b) (6)

**PARTICIPANTS:**

[Link:](#) **C** [Link:](#) Region 5

(b)(6)

**OIG – Office of Audit and Evaluation – Air Directorate**  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Julie Narimatsu, Management and Program Analyst, (312) 353-4353  
Bao Chuong, Physical Scientist, (415) 947-4533

Prepared by:	Date
Julie Narimatsu (Details section) Bao Chuong (Summary section)	5/16/19
Approved by:	Date
Renee McGhee-Lenart	5/29/19

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy points from the interview included:

(b) (6), (b) (5)

[REDACTED]

**DETAILS:**

After introductions, we discussed the topics below. (b)(6) responses are in blue text.

**Initial Background**

Renee discussed timeline received from Region 5 and when OAQPS started taking over the responsibilities for EtO facilities:

Prepared by:	Date
Julie Narimatsu (Details section)	5/16/19
Bao Chuong (Summary section)	
Approved by:	Date
Renee McGhee-Lenart	5/29/19

(b) (5)

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(b) (5)

A large rectangular area of text is completely redacted with black ink.

Renee: How did that come down? You were asked to wait?

(b) (5)

A single line of text is completely redacted with black ink.

Renee: Who asked for that to occur?

(b) (5)

A single line of text is completely redacted with black ink.

Renee then stated that we would like to discuss the directives you received from headquarters regarding EtO facilities.

We would like to know the following:

When was the meeting held/email received that provided the following directive.

Who was in the meeting or on the email chain?

Who did the directive come from?

Prepared by:	Date
Julie Narimatsu (Details section) Bao Chuong (Summary section)	5/16/19
Approved by:	Date
Renee McGhee-Lenart	5/29/19

What was the reason for the directive?

What was the impact of the directive?

Directive to stop working with ATSDR.

(b) (5)

(b) (5)

Renee: Who made the decision?

(b) (5)

Renee: Has R5 asked ATSDR to do any other health consults since that time?

(b) (5)

Renee: Have you wanted to do one and were not allowed?

(b)(6)

(b) (5)

Prepared by:	Date
Julie Narimatsu (Details section)	5/16/19
Bao Chuong (Summary section)	
Approved by:	Date
Renee McGhee-Lenart	5/29/19



(b) (5) .

Link: **B** Link: Link: (b) (5)

Renee: The rulemaking on EtO?

(b) (6), (b) (5)

Renee: Are they doing an RTR?

(b) (5)

Renee: (b) (6), (b) (5) ?

(b) (6), (b) (5)

Renee: (b) (6), (b) (5) ?

(b) (5)

Prepared by:	Date
Julie Narimatsu (Details section) Bao Chuong (Summary section)	5/16/19
Approved by:	Date
Renee McGhee-Lenart	5/29/19

(b) (5)

Renee: What was being communicated from HQ?

A [Link](#): [Link](#): [Link](#): [Link](#): [Link](#): [Link](#): (b) (5)

Renee: When was this call?

(b) (5)

[NOTE: (b) (5)]

Directive not to do monitoring or modeling at EtO facilities.

Prepared by:	Date
Julie Narimatsu (Details section)	5/16/19
Bao Chuong (Summary section)	
Approved by:	Date
Renee McGhee-Lenart	5/29/19

(b) (5)

Renee: (b) (5) ?

(b)(6) (b) (5)

Renee: Were there facilities that you wanted to do modeling?

(b) (5)

Renee: Was there any type of ambient monitoring via R5? Did the directive include R5 not doing its own ambient monitoring?

(b) (5)

Prepared by:	Date
Julie Narimatsu (Details section)	5/16/19
Bao Chuong (Summary section)	
Approved by:	Date
Renee McGhee-Lenart	5/29/19

(b) (5)

Renee: Was this nationwide or just Region 5?

(b) (5)

Renee: How did you learn of the coordinated effort?

(b) (5)

Directive not to send 114 letters to EtO facilities.

Discuss Ele where (b) (5).

(b) (5)

Prepared by:	Date
Julie Narimatsu (Details section)	5/16/19
Bao Chuong (Summary section)	
Approved by:	Date
Renee McGhee-Lenart	5/29/19

(b) (5)

Renee: Follow up of Ele - (b) (5) ?

(b) (5)

Renee: (b) (5) ?

(b) (5)

Renee: Was (b) (6) the one you learned about the directive from?

(b) (5)

(b) (5)

Renee: (b) (5) ?

(b) (5)

Prepared by:	Date
Julie Narimatsu (Details section) Bao Chuong (Summary section)	5/16/19
Approved by:	Date
Renee McGhee-Lenart	5/29/19

(b) (5)

Renee: (b) (5)

(b)(6) (b) (5)

Bao: (b) (5)

(b) (5)

Directive not to communicate with the public concerning Sterigenics, Medline, and Vantage.

When did OAQPS take over communication with the public?

When was the EtO website set up?

When did (b) (6) take over communications with Sterigenics? Did this happen at other EtO facilities?

(b) (5)

(b) (5)

(b) (5)

Prepared by:	Date
Julie Narimatsu (Details section)	5/16/19
Bao Chuong (Summary section)	
Approved by:	Date
Renee McGhee-Lenart	5/29/19

Renee: (b) (5) ?

(b) (5)

Renee: (b) (5) ?

(b) (5)

Renee: When did OAQPs take over communication?

(b) (5)

Renee: (b) (5) ?

(b)(6) (b) (5) .

Renee: (b) (5)

(b)(6) (b) (6) (b) (5) (b) (5) (b) (5)

Prepared by:	Date
Julie Narimatsu (Details section) Bao Chuong (Summary section)	5/16/19
Approved by:	Date
Renee McGhee-Lenart	5/29/19

(b) (5)

(b) (5)

Renee: Can you talk about the Sterigenics and EtO website that the public would use to figure out what they should do?

NATA was released on Aug. 22, 2018. (b) (5)

Thus, 2 hours after we gave the link to elected officials, it was taken down. (b) (5)

Renee: What were the differences in the websites? Did it address public concerns?

(b) (6) (b) (5)

Are other EPA Regions being given the same directives as EPA Region 5? If not, why?

Prepared by:	Date
Julie Narimatsu (Details section) Bao Chuong (Summary section)	5/16/19
Approved by:	Date
Renee McGhee-Lenart	5/29/19



(b) (5)

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What is the HQ action plan for the 25 EtO facilities?

(b) (5)

A large rectangular area of the document is completely blacked out, indicating redacted content.

Julie: Why did he change it to (b) (5) ?

(b) (5)

A large rectangular area of the document is completely blacked out, indicating redacted content.

Bao: Do you think block level data should be shared publicly?

Prepared by:	Date
Julie Narimatsu (Details section)	5/16/19
Bao Chuong (Summary section)	
Approved by:	Date
Renee McGhee-Lenart	5/29/19

(b) (5)

What communications are the communities near Sterigenics, Medline, and Vantage Chemicals receiving from EPA?

(b) (5)

Renee: (b) (5) ?

(b)(6) (b) (5)

Renee: And if there is any other documentation of directives through meetings, we'd be interested in those as well.

Prepared by:	Date
Julie Narimatsu (Details section)	5/16/19
Bao Chuong (Summary section)	
Approved by:	Date
Renee McGhee-Lenart	5/29/19

(b) (5)

Renee: Any communications to (b) (6) discussing the directives would be helpful.

(b) (5)

Julie: You mentioned that all the roles have recently been figured out finally; how has Region 5's relationship changed with IEPA during this matter?

(b) (5)

What is the overall impact of the communication delays and delays in taking actions such as (b) (5), etc. (Duplicate question but want to make sure we get total impact.)

(b) (5)

Prepared by:	Date
Julie Narimatsu (Details section)	5/16/19
Bao Chuong (Summary section)	
Approved by:	Date
Renee McGhee-Lenart	5/29/19

(b) (5)

Renee: (b) (5)

(b) (5)

Renee: (b) (5)

(b) (5)

Renee: (b) (5)

Prepared by:	Date
Julie Narimatsu (Details section)	5/16/19
Bao Chuong (Summary section)	
Approved by:	Date
Renee McGhee-Lenart	5/29/19

(b) (5)

Bao: I saw a news clip about dumping EtO.

(b) (5)

Renee: Do you have concerns with methodology?

(b) (5)


Bao: For the May 2018 monitoring data that came back (b) (5)

(b) (5)


Prepared by:	Date
Julie Narimatsu (Details section)	5/16/19
Bao Chuong (Summary section)	
Approved by:	Date
Renee McGhee-Lenart	5/29/19

Bao: Was the decision good for the relationship?

(b) (5)



Bao: What was the recommendation - (b) (6), (b) (5)




(b) (5)



Bao: (b) (5) ?



(b) (5)



Prepared by:	Date
Julie Narimatsu (Details section) Bao Chuong (Summary section)	5/16/19
Approved by:	Date
Renee McGhee-Lenart	5/29/19

(b) (5) (b) (5)

(b) (5)

Bao: (b) (5)

(b) (5)

Renee: Who requested the ATSDR report?

(b) (5)

Renee: Was (b) (5) ?

(b) (5)

Prepared by:	Date
Julie Narimatsu (Details section)	5/16/19
Bao Chuong (Summary section)	
Approved by:	Date
Renee McGhee-Lenart	5/29/19

Reviewer Comment (and Date of Review)	Team Response (and Date of Response)	Resolution (and Date of Resolution)
Minor revisions made.		WP approved. RML 5/29/19

Prepared by:	Date
Julie Narimatsu (Details section) Bao Chuong (Summary section)	5/16/19
Approved by:	Date
Renee McGhee-Lenart	5/29/19



**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.03.b**

**PURPOSE:** To interview (b)(6) regarding EPA's role in addressing ethylene oxide and chloroprene emissions.

**SCOPE:** Interviewed (b)(6) regarding EPA's role in addressing ethylene oxide and chloroprene emissions.

**SOURCE:** A) See list of participants below.

B) OAQPS-developed list of high-risk ethylene oxide facilities as of 8/21/18. (Received from (b) (6) on 6/7/18.)

C) OAQPS-developed list of high-risk ethylene oxide facilities as of 8/6/18. (Received from (b) (6) on 6/7/18.)

**DATE and TIME:** 7/15/19, 3:00 – 4:00 PM CDT.

**LOCATION:** (b) (6)

**PARTICIPANTS:**

**Link:** (b)(6)

**OIG – Office of Audit and Evaluation – Air Directorate**  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy points from the interview included:

- (b) (6), (b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	7/29/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	8/1/19

(b) (6), (b) (5)

**DETAILS:**

After introductions, Renee provided background information on our assignment. She explained that initially, we sent out a notification memo with an objective to determine whether EPA's residual risk and technology review process has sufficiently identified and addressed any elevated cancer risks from air toxics emitted by facilities. We then received four Congressional requests related to ethylene oxide. Our management decided to have us address the four Congressional requests. We have decided that we will write a report to address the four Congressional requests.

As a result of the four Congressional requests, we have expanded the scope to address the following Congressional questions:

- Whether EPA senior political appointees instructed EPA inspectors to avoid conducting inspections at EtO emitting facilities across EPA Regions 5 and 6.
- Have inspections by the EPA been conducted on [ethylene oxide-emitting] facilities in Regions 5 and 6? If not, why?
- Whether the EPA complied with all statutory, regulatory and policy requirements and protocols in disclosing public health information about ethylene oxide air emissions from the Sterigenics facility in DuPage County, Illinois, the Medline Industries, Inc. facility in Lake County, Illinois and the Vantage Specialty Chemicals, Inc. facility in Lake County, Illinois.

After providing the background, Renee then proceeded to ask the following questions. (b) (6) response is in blue text.

Background on (b)(6)

1. What is your title or role?

(b)(6)

2. How long have you been in your current position?

(b) (6)

Prepared by:	Date
Bao Chuong	7/29/19
Approved by:	Date
Renee McGhee-Lenart	8/1/19

3. Who do you report to?

(b) (6)

#### HQ Directives

4. Do you have knowledge of the following HQ directives or heard of the following HQ directives?

- Directive not to conduct inspections at ethylene oxide facilities. (b) (5)
- Directive not to conduct monitoring at ethylene oxide facilities. (b) (5) [Link: WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.doc](#) (b) (5)
- Directive not to do modeling at ethylene oxide facilities. (b) (5)
- Directive not to send 114 letters to ethylene oxide facilities. (b) (5)

#### Ethylene Oxide

5. Please describe what your division is working on in regards to ethylene oxide facilities in Region 6?

(b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	7/29/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	8/1/19

(b) (5)

#### Section 114 Letter to Denka

6. We understand that on December 18, 2015, Region 6 sent a 114 letter to Denka to obtain information necessary to determine compliance with the Clean Air Act, the emissions inventory requirements of the Louisiana SIP, and the facility permit. Subsequently, NEIC, along with 3 Region 6 air inspectors and an LDEQ inspector, conducted an onsite inspection of Denka from June 6 – 10, 2016.

- a. What was the impetus for assessing compliance at Denka? Was it due to the 2011 NATA showing elevated cancer risks attributed to chloroprene emissions from Denka?

(b) (6), (b) (5)

- b. Similarly, has Region 6 sent a 114 letter to any ethylene oxide facilities in the region? If not, why not?

(b) (6), (b) (5)

- c. Similarly, does Region 6 plan to inspect any of the ethylene oxide facilities in the region? If not, why not?

(b) (5)

- d. Does Region 6 have a policy to assess compliance when NATA results show a facility contributing to elevated cancer risk?

(b) (5)

(b) (6)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	7/29/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	8/1/19

#### Onsite Visit of Denka May 18, 2016

7. We understand that OAQPS conducted a site visit of Denka on May 18, 2016 to gather information on the processes and air pollution controls at the facility.
- a. Did staff from Region 6 participate in the site visit?

(b) (6), (b) (5)

#### Current NESHAP for Group I Polymers and Resins

8. Do you think the current NESHAP for Group 1 polymers and resins is protective of human health? If not, what existing standards need to be revised or what new standards need to be implemented?

I have no idea. I'm not a chemist. I'm not a scientist either.

#### Onsite Inspection of Denka June 6-10, 2016

9. We understand that EPA's NEIC conducted an onsite inspection of Denka from June 6 to June 10, 2016, and that three Region 6 air inspectors and one LDEQ inspector participated in the inspection.
- a. What were the inspection findings?

(b) (5)

- b. Did you review the inspection report?

(b) (5)

10. Did the inspection result in any enforcement actions taken against Denka? If so, please elaborate.

(b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	7/29/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	8/1/19

11. Has NEIC, Region 6, or LDEQ conducted another inspection to verify that violations have been corrected? If so, when did the inspection take place and has Denka corrected all violations?

(b) (5)

12. Have there been times since January 2017 when Region 6 wanted to conduct an onsite inspection at Denka or other facilities but was told not to? If so, please elaborate.

(b) (5)

13. Have there been times since January 2017 when Region 6 wanted to send a 114 letter to Denka or other facilities but was told not to? If so, please elaborate.

(b) (5)

14. Have there been times since January 2017 when Region 6 wanted to take an enforcement action against Denka or other facilities but was told not to? If so, please elaborate.

(b) (5)

15. Have there been times since January 2017 when Region 6 wanted Denka or other facilities to conduct its own monitoring, such as monitoring for fugitive emissions? Please elaborate.

(b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	7/29/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	8/1/19

## State Inspections

16. Has LDEQ conducted onsite inspections of Denka since June 2016?

(b) (6), (b) (5)

(b) (5)

a. Did LDEQ take any enforcement actions? If so, please elaborate.

(b) (5)

17. Are Region 6 states conducting inspections at ethylene oxide facilities in a timely manner using the agreed upon dates in their approved state compliance monitoring plan? How does Region 6 determine that the states are conducting these inspections in a timely manner?

(b) (5)

(b) (5)

## IRIS Assessments

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	7/29/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	8/1/19

19. Prior to the development of the 2011 NATA by OAQPS, were you aware that the IRIS program issued a new IRIS assessment for chloroprene in September 2010?

(b) (5)

20. Prior to the development of the 2014 NATA by OAQPS, were you aware that the IRIS program issued a new IRIS assessment for ethylene oxide in December 2016?

(b) (5)

Reviewer Comment (and Date of Review)	Team Response (and Date of Response)	Resolution (and Date of Resolution)
No comments. RML 8/1/19		WP approved. RML 8/1/19

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	7/29/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	8/1/19



**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.03.c**

**PURPOSE:** To interview (b)(6) regarding EPA's role in addressing ethylene oxide and chloroprene emissions.

**SCOPE:** Interviewed (b)(6) regarding EPA's role in addressing ethylene oxide and chloroprene emissions.

**SOURCE:** A) See list of participants below.

B) OAQPS-developed list of high-risk ethylene oxide facilities as of 8/21/18. (Received from (b)(6) on 6/7/18.)

C) OAQPS-developed list of high-risk ethylene oxide facilities as of 8/6/18. (Received from (b)(6) on 6/7/18.)

**DATE and TIME:** 7/17/19, 2:30 – 3:30 PM CDT.

**LOCATION:** (b)(6)

**Link:** [WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docx](#)**PARTICIPANTS:**

(b)(6)

**OIG – Office of Audit and Evaluation – Air Directorate**  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Andrew Lavenburg, Social Scientist, (919) 541-1871 (by phone)  
Bao Chuong, Physical Scientist, (415) 947-4533

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy points from the interview included:

- (b)(5), (b)(6)
- 

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	8/30/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	9/03/19

- (b) (6), (b) (5)

#### DETAILS:

After introductions, Renee provided background information on our assignment. She explained that initially, we sent out a notification memo with an objective to determine whether EPA's residual risk and technology review process has sufficiently identified and addressed any elevated cancer risks from air toxics emitted by facilities. We then received four Congressional requests related to ethylene oxide. Our management decided to have us address the four Congressional requests. We have decided that we will write a report to address the four Congressional requests.

As a result of the four Congressional requests, we have expanded the scope to address the following Congressional questions:

- Whether EPA senior political appointees instructed EPA inspectors to avoid conducting inspections at EtO emitting facilities across EPA Regions 5 and 6.
- Have inspections by the EPA been conducted on [ethylene oxide-emitting] facilities in Regions 5 and 6? If not, why?
- Whether the EPA complied with all statutory, regulatory and policy requirements and protocols in disclosing public health information about ethylene oxide air emissions from the Sterigenics facility in DuPage County, Illinois, the Medline Industries, Inc. facility in Lake County, Illinois and the Vantage Specialty Chemicals, Inc. facility in Lake County, Illinois.

After providing the background, Renee then proceeded to ask the following questions. (b) (6) response is in blue text.

Background on (b)(6)

1. What is your title or role?

(b)(6)

2. How long have you been in your current position?

Prepared by:	Date
Bao Chuong	8/30/19
Approved by:	Date
Renee McGhee-Lenart	9/03/19

(b) (6)

3. Who do you report to?

(b) (6)

#### HQ Directives

4. Do you have knowledge of the following HQ directives or heard of the following HQ directives?

- Directive not to conduct inspections at ethylene oxide facilities. (b) (5)
- Directive not to conduct monitoring at ethylene oxide facilities. (b) (5)
- Directive not to do modeling at ethylene oxide facilities. (b) (5)
- Directive not to send 114 letters to ethylene oxide facilities. (b) (5)

#### OAR's Two-Pronged Approach to Address Ethylene Oxide-Emitting Facilities

5. As you may know, OAR developed and rolled out a two-pronged approach to address ethylene oxide-emitting facilities. Prong 1 is rulemaking, such as issuing RTR rules. What have you heard about Prong 2? For example, what are the goals and milestones for Prong 2?

(b) (5)

(b) (5)

(b) (5)

Link: (b) (5)  
Link: WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docx (b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	8/30/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	9/03/19

The 2014 NATA that was released to the public was based on the 2014 NEI data. (b) (5)

(b) (5)

(b) (5)

(b) (5)

6. (b) (6), (b) (5)

(b) (5)

(b) (5)

#### High-Risk Ethylene Oxide-Emitting Facilities in Region 6

7. We understand that during the development of the 2014 NATA, OAQPS sent drafts of NATA to states and regions for review.

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	8/30/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	9/03/19

- a. After reviewing the 2014 NATA drafts, did Region 6 conduct its own air quality dispersion modeling of ethylene oxide facilities? (b) (5)

- b. Did Region 6 reach out to facilities to confirm the emissions data being used for the 2014 NATA development?

(b) (5)

(b) (5)

- i. If so, which facilities and were they responsive to Region 6's outreach?

See response above.

- ii. At any time, did Region 6 consider sending 114 letters to any of the facilities to confirm or obtain emissions data? If so, for which facilities? Did Region 6 send any 114 letters to these facilities? If not, why not?

(b) (5)

- c. Did the region conduct any other activities to confirm the preliminary 2014 NATA emissions data?

(b) (5)

8. We understand that OAQPS developed a list of high-risk ethylene oxide-emitting facilities that regions are to focus on.

- a. What criteria was used to develop the list of facilities? (b) (5)

(b) (5)

- b. What are OAQPS' expectations of the regions with respect to the high-risk facilities?

(b) (5)

- c. What are Region 6's plans with regards to the high-risk facilities?

(b) (5), (b) (6)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	8/30/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	9/03/19

- d. Are there any milestone dates associated with regional activities at the high-risk facilities?

(b) (5)

[Link: WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docx](#) (b) (5)

- e. Since the release of the 2014 NATA to the public,

- i. How many of the high-risk facilities has Region 6 communicated with?

(b) (5)

- ii. What actions has Region 6 taken with respect to the high-risk facilities?

[See response to Question 5.](#)

- iii. What voluntary reductions, if any, has Region 6 pursued with the 10 high-risk facilities?

(b) (5)

- iv. Are there any plans to inspect any of the 10 high-risk facilities? Why or why not?

(b) (5)

- f. We understand that the initial list of high-risk facilities (b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	8/30/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	9/03/19

(b) (5)

ii. (b) (5)

(b) (5)

- g. We understand that the 2014 NATA shows census tracts around Denka having total cancer risks attributed to both chloroprene and ethylene oxide emissions. Has Region 6 informed the community of the higher cancer risks due to both chloroprene and ethylene oxide emissions?

(b) (5)

- h. We understand that on December 18, 2015, EPA sent a 114 letter to Denka to obtain information necessary to determine compliance with the Clean Air Act, the emissions inventory requirements of the Louisiana SIP, and the facility permit. Subsequently, NEIC, along with 3 Region 6 air inspectors and an LDEQ inspector, conducted an onsite inspection of Denka from June 6 – 10, 2016.

- i. Similarly, has Region 6 sent a 114 letter to any ethylene oxide facilities in the region? If not, why not?

(b) (5)

- ii. Similarly, does Region 6 plan to inspect any of the ethylene oxide facilities in the region? If not, why not?

(b) (5)

(b) (5)

(b) (5)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	8/30/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	9/03/19

(b) (5) (b) (5)

#### Public Outreach in Communities Where the High-Risk Facilities Are Located

10. Does EPA have to follow any statutory, regulatory, and/or policy requirements and protocols to disclose public health information about emissions of hazardous air pollutants, such as ethylene oxide and chloroprene?

(b) (5) We are required to conduct NATA and issue results of NATA every 3 years. (b) (5)  
(b) (6)

11. (b) (5)

- a. How many communities (i.e., town/city where facility is located) has Region 6 reached out to about the 2014 NATA results?

(b) (5) (b) (5)

(b) (5) (b) (6)

- b. By what means (e.g., public meetings, webinars) has Region 6 reached out to the communities?

(b) (5) (b) (5)

- c. How have the communities reacted to Region 6's outreach efforts?

Did not ask since (b) (6) did not know how Region 6 reached out to communities. See response to 11.b.

- d. Has Region 6 reached out to advocacy groups where (b) (5)

See response to 11.a.

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	8/30/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	9/03/19



e. Has Region 6 reached out to elected officials (b) (5)

f. What needs or requests have communities, advocacy groups, and elected officials asked of Region 6? Has Region 6 been able to meet their needs or requests?

See response to 11.a.

g. We understand that a (b) (5)

(b) (5)

#### Ambient Monitoring Around Ethylene Oxide Facilities

12. We understand that one of the reasons EPA conducted ambient monitoring around Denka was

(b) (5)

Why or why not?

(b) (5)

(b) (5)

#### IRIS Assessments

13. Prior to the development of the 2011 NATA by OAQPS, were you aware that the IRIS program issued a new IRIS assessment for chloroprene in September 2010?

(b) (6)

14. Prior to the development of the 2014 NATA by OAQPS, were you aware that the IRIS program issued a new IRIS assessment for ethylene oxide in December 2016?

Prepared by:	Date
Bao Chuong	8/30/19
Approved by:	Date
Renee McGhee-Lenart	9/03/19

(b) (6), (b) (5)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Reviewer Comment (and Date of Review)	Team Response (and Date of Response)	Resolution (and Date of Resolution)
No comments. RML 9/03/19		WP approved. RML 9/3/19

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	8/30/19
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	9/03/19

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.03.d**

**PURPOSE:** Obtain information regarding the Office of Air Quality Planning & Standards (OAQPS) role in addressing ethylene oxide and chloroprene emissions from stationary sources.

**SCOPE:** This workpaper summarizes an interview with (b)(6) to obtain information about (b)(6) knowledge of how EPA worked to address ethylene oxide and chloroprene emissions from certain facilities in Regions 5 and 6.

**SOURCE:** See the list of meeting participants below.

**DATE and TIME:** 1/5/21, 12:00pm – 1:00pm CST.

**LOCATION:** Microsoft Teams Conference Call.

**PARTICIPANTS:**

(b)(6)

**OIG – Office of Audit and Evaluation – Air Directorate**  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Bao Chuong, Physical Scientist, (415) 947-4533  
Andrew Lavenburg, Social Scientist, (919) 541-1871  
Julie Narimatsu, Team Lead, (312) 353-4353

**CONCLUSION:** No conclusions drawn from this one meeting.

**DETAILS:**

Prior to the interview, Ms. McGhee-Lenart provided some background on the OIG audit, explained the audit objective, and also provided the key questions that members of Congress had ask OIG to evaluate.

Questions asked by OIG during the interview are in black font, below, with a summary of the discussion in response to each question provided in blue font.

<b>Prepared by:</b>	<b>Date</b>
Julie Narimatsu	1/7/21
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	1/12/21

(b)(6) asked if the congressional focused on ethylene oxide or was it other pollutants as well. Renee responded the Congressional focused on ethylene oxide, including whether EPA appointees made instructions to regional employees not to conduct inspections at facilities that emit ethylene oxide. The Congressional requests were focused on Regions 5 and 6.

**Background on (b)(6)**

1. How long have you been (b)(6) ?

(b) (6)

2. Are you a career civil servant? Or a political appointee?

(b)(6) Career civil servant.

3. Who do you report to?

(b)(6)

4. What is your role in handling issues concerning ethylene oxide?

(b)(6) (b) (5)

**Two-Pronged Approach**

5. Please provide us some background on how the two-pronged approach was developed and what the goals of the strategy are?

(b) (5)

Prepared by:	Date
Julie Narimatsu	1/7/21
Approved by:	Date
Renee McGhee-Lenart	1/12/21

(b) (5)

6. We understand that Region 5 had a webpage on Sterigenics that went live while the 2014 NATA webpage went live. We also understand that the Region 5 webpage on Sterigenics was live for about an hour (b) (6) ordered Region 5 to pull the webpage down. Do you know why (b) (6) requested that the webpage be taken down? Did you have any concerns about the Region 5 webpage?

(b)(6) No.

Renee: Did you hear about it?

(b) (5)

Renee: You hadn't had a chance to review the R5 website or had concerns?

(b)(6) No, I wouldn't have reviewed the Region 5 website.

(b) (6), (b) (5)

7. We understand that Region 5 (b) (6), (b) (5)

(b) (6), (b) (5)

(b) (6), (b) (5)

#### Instructions Not to Send CAA Section 114 Letters to Facilities

8. We understand that the second prong of the two-pronged approach to address ethylene oxide emissions involves gathering information. However, we learned that Region 5 staff were told not to issue Section 114 letters to ethylene oxide facilities.
- Who issued the instructions?
  - Why were these instructions issued?
  - Was the same directive issued to other regions?

Prepared by:	Date
Julie Narimatsu	1/7/21
Approved by:	Date
Renee McGhee-Lenart	1/12/21

(b)(6) (b) (5)

Drew: Something we've heard related to 114 letters is that they're not really consistent with the Two-Pronged strategy to voluntarily work with industry. Would you characterize it as such? We hear about it as a tool in different ways from different people. How are they used as part of the strategy for getting more information generally speaking?

(b)(6) (b) (5)

Drew: Would OAQPS coordinate with regions as part of rulemaking or do regions have autonomy?

(b)(6) (b) (5)

Drew: With the possibility of a regulation down the road, you might need a 114, but a region is looking at it from an enforcement side – there might be different reasons.

(b)(6) (b) (5)

Bao: We understand that OAQPS had completed quite a few RTR (risk and technology review) rulemakings in the last couple of years. Were there any instructions from the OAR immediate

Prepared by:	Date
Julie Narimatsu	1/7/21
Approved by:	Date
Renee McGhee-Lenart	1/12/21

office not to send 114 letters out unless OAQPS gets approval from someone? What was the general message from the immediate office regarding RTR rulemakings and 114?

(b) (5)



#### **Instructions to Get Permission from OAQPS to Conduct Modeling**

9. We understand that Region 5 was told to seek permission from OAQPS before conducting any modeling on ethylene oxide facilities.
  - a. Who instructed Region 5 to get permission from OAQPS to conduct modeling?
  - b. Why was this instruction given to Region 5?
  - c. Was the same instruction given to other regions?

(b) (5)



Renee: Who instructed Region 5 get permission from OAQPS to do modeling?

(b) (5)



#### **Instructions Not to Conduct Monitoring**

10. We understand that OAQPS completed ambient monitoring of Sterigenics in Willowbrook. We also understand that the agency won't be conducting monitoring of ethylene oxide emissions from other facilities.
  - a. Whose decision was it that EPA won't be conducting monitoring of ethylene oxide emissions from other facilities?
  - b. What was the reasoning for this decision?

Prepared by:	Date
Julie Narimatsu	1/7/21
Approved by:	Date
Renee McGhee-Lenart	1/12/21

(b) (5)

Renee: Any other monitoring that has taken place other than Sterigenics?

(b) (5)

Renee: But you're not aware of any instructions not to conduct monitoring?

(b) (5)

#### Instructions Not to Seek the Assistance from ATSDR

11. We understand that Region 5 was told to no longer seek assistance from ATSDR.

- a. Who directed Region 5 to no longer seek assistance from ATSDR?
- b. Why was this instruction issued?

(b) (5)

Renee: I know you talked about the different roles and strategic matters and such. The person we talked to is (b) (6). Is one of (b) (6) roles is to be a point person for EtO?

(b)(6) Yes. (b) (5)

Prepared by:	Date
Julie Narimatsu	1/7/21
Approved by:	Date
Renee McGhee-Lenart	1/12/21



(b) (5)

Renee: I'll give you an update on where we are. We are doing two separate reports and they'll be coming your way in a matter of weeks. The first one is the main one – that will come first. And then afterwards will be the congressional. We did split them up. You'll have the full time to review the first before the next one comes out.

(b)(6) Was your goal to look broadly at the RTR program or was it more specific?

Renee: It was more specific, focusing initially on EtO and chloroprene – those specific areas because of the toxic risks and IRIS values ended up going up for both. We were more focused on those pollutants and not the whole process. But we do provide background on the whole process to provide context.

(b) (5)

Renee: (b) (5)

Do you mind if we contact you if we have any follow-up?

(b) (6)

Reviewer Comment (and Date of Review)	Team Response (and Date of Response)	Resolution (and Date of Resolution)
Minor changes. RML 1/12/21		WP approved. RML 1/12/21

<b>Prepared by:</b>	<b>Date</b>
Julie Narimatsu	1/7/21
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	1/12/21

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.04.a**

**PURPOSE:** To discuss with Region 5 (b) (6) about the region's role in addressing ethylene oxide emissions.

**SCOPE:** Interviewed Region 5 (b) (6) about the region's role in addressing ethylene oxide emissions.

**SOURCE:** A) See the list of meeting participants below.

**DATE and TIME:** 4/2/19, 3:00 – 3:30 PM CDT.

**LOCATION:** (b) (6).

**PARTICIPANTS:**

(b)(6)

**OIG – Office of Audit and Evaluation – Air Directorate**  
Renee McGhee-Lenart, Project Manager, (913) 551-7534  
Julie Narimatsu, Management and Program Analyst, (312) 353-4353  
Bao Chuong, Physical Scientist, (415) 947-4533

Prepared by:	Date
Julie Narimatsu (Details Section) Bao Chuong (Summary Section)	5/14/19
Approved by:	Date

**CONCLUSION:** No conclusions drawn from this one meeting.

**SUMMARY:** Noteworthy points from the interview included:

- (b) (5), (b) (6)

[REDACTED]

**DETAILS:**

After introductions, we discussed the following topics and asked questions related to the topics. Blue text are Region 5 responses.

**How the Air Enforcement Branch Addressed Ethylene Oxide-Emitting Facilities**

1. Bao: What was your concern/response about ethylene oxide (EtO) facilities?

(b) (5)

2. Bao: Can you talk about (b) (5)

Prepared by:	Date
Julie Narimatsu (Details Section) Bao Chuong (Summary Section)	5/14/19
Approved by:	Date

(b) (5)

3. Bao: What about Ele?

(b) (5)

4. Bao: (b) (5)

(b) (5)

5. Renee: (b) (5)

(b) (5)

6. Renee: (b) (5)

(b) (5)

7. Bao: (b) (5)

(b) (5)

Prepared by:	Date
Julie Narimatsu (Details Section) Bao Chuong (Summary Section)	5/14/19
Approved by:	Date

8. Bao: (b) (5)

(b) (5)

#### Addressing Minor Facilities

9. Renee: Do you do a PCE only if there's a focused problem that you want to look at?

(b)(6) (b) (5)

10. Renee: How are states inspecting minor facilities?

(b) (5)

(b)(6) (b) (5)

(b) (5)

11. Renee: Why were you told to hold off – temporarily?

(b) (5)

Prepared by:	Date
Julie Narimatsu (Details Section) Bao Chuong (Summary Section)	5/14/19
Approved by:	Date

**Directive Not to Send CAA Section 114 Letters**

12. Renee: Can you discuss the directive of not sending out 114 letters?

(b) (5)

(b) (5)

(b) (5)

13. Renee: Did that affect you?

(b) (5) We strictly focused on the EtO side.

(b) (6), (b) (5)

Prepared by:	Date
Julie Narimatsu (Details Section) Bao Chuong (Summary Section)	5/14/19
Approved by:	Date

16. Renee: Did they act on your behalf?

(b) (5)

17. Renee: (b) (5) ?

(b)(6) (b) (5) .

(b)(6) (b) (5) .

18. Renee: (b) (5) ?

(b) (5) .

19. Renee: (b) (5)

(b)(6) (b) (5)

#### More on Inspections and Enforcement

20. Renee: (b) (5) ?

(b) (5)

Prepared by:	Date
Julie Narimatsu (Details Section) Bao Chuong (Summary Section)	5/14/19
Approved by:	Date

21. Julie: Is this normal? (b) (5) ?

(b)(6) (b) (5)

22. Bao: What about (b) (5) ?

(b)(6) (b) (5)

23. Bao: Even with administration changes?

(b)(6) (b) (5)

(b)(6) (b) (5)

24. Bao: (b) (5) ?

(b) (5)

25. Bao: (b) (5) ?

(b)(6) (b) (5)

(b) (5)

(b)(6) (b) (5)

Prepared by:	Date
Julie Narimatsu (Details Section) Bao Chuong (Summary Section)	5/14/19
Approved by:	Date



26. Renee: Are there any plans for inspections?

(b) (5)

27. Renee: If they'd gotten the green light, would you know?

(b) (5)

28. Renee: In terms of OECA priorities, are there any coming out?

(b) (5)

29. Renee: Have the states had any significant findings?

(b) (5)

(b) (5)

Prepared by:	Date
Julie Narimatsu (Details Section) Bao Chuong (Summary Section)	5/14/19
Approved by:	Date

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP H.04.b**

**PURPOSE:** Obtain information regarding Region 6's role in addressing ethylene oxide and chloroprene emissions from stationary sources.

**SCOPE:** This workpaper summarizes an interview with (b)(6) of EPA Region 6, to obtain information about (b)(6) knowledge of how EPA Region 6 works to address ethylene oxide and chloroprene emissions.

**SOURCE:** See the list of meeting participants below.

- A) Email from (b)(6), providing OIG with Region 6 ethylene oxide enforcement action plan.
- B) Region 6 ethylene oxide enforcement action plan.
- C) Email from (b)(6), providing OIG with the original draft Region 6 ethylene oxide enforcement action plan.
- D) Original draft Region 6 ethylene oxide enforcement action plan.

**DATE and TIME:** 7/17/19, 9:00am – 10:30am CDT.

**LOCATION:** (b)(6).

**PARTICIPANTS:**

Link: (b)(6)

[Redacted]

**OIG – Office of Audit and Evaluation – Air Directorate**

Renee McGhee-Lenart, Project Manager, (913) 551-7534

Bao Chuong, Physical Scientist, (415) 947-4533

Andrew Lavenburg, Social Scientist, (919) 541-1871 (participated in meeting via telephone)

**CONCLUSION:** No conclusions drawn from this one meeting.

**DETAILS:**

Prior to the interview, Ms. McGhee-Lenart provided some background on the OIG audit, explained the audit objective and also provided the key questions that members of Congress had ask OIG to evaluate.

Preparer's Initials and Date	
AJL	7/29/19 Page 342 of 383
RML	Approved on 8/1/19

Questions asked by OIG during the interview are in black font, below, with a summary of the discussion in response to each question provided in blue font.

Background on (b)(6)

1. What is your title or role?

(b)(6)

(b)(6)

2. How long have you been in your current position?

(b) (6)

(b) (6)

3. Who do you report to?

(b)(6)

#### Air Toxics Enforcement Section

4. What is the mission of the Air Toxics Enforcement Section?

(b)(6) said that their mission is to ensure compliance with the NESHAP portion of the Clean Air Act. (b) (6) looks at facilities emitting toxics near communities. They also have a state oversight function, and Freedom of Information Act (FOIA) function (b) (6).

5. Are inspections from your section focused primarily on compliance with NESHAP standards?

(b) (6) is primarily focused on compliance with NESHAP standards.

Preparer's Initials and Date	
AJL	7/29/19
RML	Approved on 8/1/19

## HQ Directives

6. Do you have knowledge of the following HQ directives or heard of the following HQ directives?

- Directive not to conduct inspections at ethylene oxide facilities.

(b) (5), (b) (6)

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- Directive not to conduct monitoring at ethylene oxide facilities.

(b) (5)

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(b) (6), (b) (5)

(b) (5)

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Preparer's Initials and Date	
AJL	7/29/19
RML	Approved on 8/1/19

(b) (5)

Mr. Chuong asked which facilities in St. John the Baptist Parish in Louisiana that were contributing to elevated cancer risk due to ethylene oxide and impacting the LaPlace community (b) (5)

(b) (5)

- Directive not to do modeling at ethylene oxide facilities.

(b) (6), (b) (5)

(b) (6), (b) (5)

- Directive not to send 114 letters to ethylene oxide facilities.

(b) (6), (b) (5)

(b) (6), (b) (5)

(b) (6), (b) (5)

(b) (6), (b) (5)

(b) (6), (b) (5)

Preparer's Initials and Date	
AJL	7/29/19
RML	Approved on 8/1/19

Mr. Chuong asked if Regions needed Headquarters approval to send out 114 letters prior to the administration change. (b) (6), (b) (5)

Mr. Chuong asked if the current Headquarters restrictions on sending out 114 letters have had an impact on the number of inspections conducted in the Region and the number of enforcement cases pursued by the Region. (b) (6), (b) (5)

Mr. Chuong asked whether the total number of inspections – offsite plus onsite – have gone down since the administration change in 2017. (b) (6), (b) (5)

Mr. Chuong asked if there were times where the Region could not determine compliance from an on-site inspection and needed a 114 letter. (b) (6), (b) (5)

(b) (5)


Ms. McGhee-Lenart asked if managers in other Regions had raised concerns about this. (b) (6), (b) (5)

Preparer's Initials and Date	
AJL	7/29/19
RML	Approved on 8/1/19

## Ethylene Oxide

7. [Link:Link:](#)**A** Please describe the work you both have done with ethylene oxide facilities in Region 6?

(b) (6), (b) (5)



Preparer's Initials and Date	
AJL	7/29/19
RML	Approved on 8/1/19

(b) (5)

Evaluator Note- (b)(6) provided OIG with a copy of the action plan (see Source A [Link](#): for email from (b)(6), and Source B [Link](#): for a copy of the action plan) (b)(6) provided OIG with the original draft version of the action plan, prior to edits and revisions made by Region 6 management and/or EPA Headquarters (see Source C [Link](#): for e-mail from (b)(6), and Source D [Link](#): for original draft action plan).

According to (b) (5)

Ms. McGhee-Lenart asked (b)(6) describe what the purpose of (b)(6) paper was (b) (5)

Mr. Chuong asked if EPA Headquarters wanted a separate communication plan, in addition to the action plan that was developed. (b) (5)

Mr. Chuong asked what they had heard about the 2 prong strategy. (b) (5)

[Link](#): WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docx Mr. Chuong asked if EPA Headquarters provided Region 6 with milestones or deadlines as to when they needed to talk to all facilities after the 2014 NATA release. (b) (5)

(b) (6), (b) (5)

Preparer's Initials and Date	
AJL	7/29/19
RML	Approved on 8/1/19



[Link: WP E.08.a - Addressing EtO Facilities Thru 2-Pronged Approach.docx](#) Mr. Chuong asked what was expected of each Region with regards to the 2 prong approach (i.e., what are the goals of this strategy?). (b) (5)

(b) (5)

(b) (5)

Mr. Chuong asked if Region 6 asked any of the facilities for more accurate modeling parameters when they reached out to facilities to confirm emissions after they were identified as high risk facilities from the NATA. (b) (5)

(b) (5)

#### Section 114 Letter to Denka

8. We understand that on December 18, 2015, Region 6 sent a 114 letter to Denka to obtain information necessary to determine compliance with the Clean Air Act, the emissions inventory requirements of the Louisiana SIP, and the facility permit. Subsequently, NEIC, along with 3 Region 6 air inspectors and an LDEQ inspector, conducted an onsite inspection of Denka from June 6 – 10, 2016.
  - a. What was the impetus for assessing compliance at Denka? Was it due to the 2011 NATA showing elevated cancer risks attributed to chloroprene emissions from Denka?

(b) (5)

- b. Similarly, has Region 6 sent a 114 letter to any ethylene oxide facilities in the region? If not, why not?

(b) (6), (b) (5)

Preparer's Initials and Date	
AJL	7/29/19
RML	Approved on 8/1/19

- c. Similarly, does Region 6 plan to inspect any of the ethylene oxide facilities in the region? If not, why not?

Question not asked during interview.

- d. Does Region 6 have a policy to assess compliance when NATA results show a facility contributing to elevated cancer risk?

(b) (6), (b) (5)

#### Onsite Visit of Denka May 18, 2016

9. We understand that OAQPS conducted a site visit of Denka on May 28, 2016 to gather information on the processes and air pollution controls at the facility.
- a. Did you or anyone from Region 6 participate in the site visit? If so, please provide a high-level overview of what was found.

(b) (6), (b) (5)

- b. Do you know whether any of the information found will be used in a potential new risk and technology review?

Question not asked due to response to 9.a.

#### Current NESHAP for Group I Polymers and Resins

10. Do you think the current NESHAP for Group 1 polymers and resins is protective of human health? If not, what existing standards need to be revised or what new standards need to be implemented?

Preparer's Initials and Date	
AJL	7/29/19
RML	Approved on 8/1/19

(b) (5)

(b) (6), (b) (5)

Mr. Chuong asked if it would be better to have a rule in place, given (b) (5)  
(b) (5)  
(b) (5)

#### Onsite Inspection of Denka June 6-10, 2016

11. We understand that EPA's NEIC conducted an onsite inspection of Denka from June 6 to June 10, 2016, and that three Region 6 air inspectors (b) (5) and one LDEQ inspector participated in the inspection.

a. Did the three Region 6 air inspectors brief you on what they found during the inspection?

(b) (6), (b) (5)

b. Were you involved with reviewing the inspection report?

(b) (6), (b) (5)

12. Did the inspection result in any enforcement actions taken against Denka? If so, please elaborate.

(b) (5)

Preparer's Initials and Date	
AJL	7/29/19
RML	Approved on 8/1/19

13. (b) (6), (b) (5)

14. If Denka has corrected all violations, has ambient concentrations of chloroprene decreased to the point that it's not resulting in a 100-in-1 million cancer risk?

Question not asked due to the response to Question #12.

15. Have there been times since January 2017 when you or someone else in Region 6 wanted to conduct an onsite inspection at Denka or other facilities but was told not to? If so, please elaborate.

(b) (6), (b) (5)

16. Have there been times since January 2017 when you or someone else in Region 6 wanted to send a 114 letter to Denka or other facilities but was told not to? If so, please elaborate.

(b) (6), (b) (5)

17. Have there been times since January 2017 when you or someone else in Region 6 wanted to take an enforcement action against Denka or other facilities but was told not to? If so, please elaborate.

(b) (6), (b) (5)

Preparer's Initials and Date	
AJL	7/29/19
RML	Approved on 8/1/19

18. Have there been times since January 2007 when you or someone else in Region 6 wanted Denka or other facilities to conduct its own monitoring, such as monitoring for fugitive emissions? Please elaborate.

(b) (6), (b) (5)

#### State Inspections

19. Has LDEQ conducted onsite inspections of Denka since June 2016?

- a. If so, when were the state inspections?

(b) (6), (b) (5)

- b. Did you or anyone else from Region 6 participate in the inspections?

Question not asked due to response to 19.a

- c. Did LDEQ take any enforcement actions? If so, please elaborate.

Question not asked due to response to 19.a

20. Are Region 6 states conducting inspections at ethylene oxide facilities in a timely manner using the agreed upon dates in their approved state compliance monitoring plan? How does Region 6 determine that the states are conducting these inspections in a timely manner?

(b) (6), (b) (5)

(b) (5)

Preparer's Initials and Date	
AJL	7/29/19
RML	Approved on 8/1/19

21. (b) (5)

(b)(6)

#### IRIS Assessments

22. Prior to the development of the 2011 NATA by OAQPS, were you aware that the IRIS program issued a new IRIS assessment for chloroprene in September 2010?

(b) (6), (b) (5)

23. Prior to the development of the 2014 NATA by OAQPS, were you aware that the IRIS program issued a new IRIS assessment for ethylene oxide in December 2016?

(b) (5)

Reviewer Comment (and Date of Review)	Team Response (and Date of Response)	Resolution (and Date of Resolution)
No comments.		WP approved. RML 8/1/19

Preparer's Initials and Date	
AJL	7/29/19
RML	Approved on 8/1/19

**Evaluation of EPA Actions to Address Elevated Cancer Risks from Air Toxics Emissions from Point Sources**  
**OA&E-FY19-0091**  
**WP L.14**

**PURPOSE:** To summarize interviewee responses on whether HQ directives were issued regarding how Region 5 and Region 6 could address the ethylene oxide issue.

**SCOPE:** Reviewed write-ups of meetings and interviews with Region 5, Region 6, the Office of Air Quality Planning and Standards (OAQPS), and the Office of Enforcement and Compliance Assurance (OECA) personnel to summarize whether directives were issued.

**SOURCE:** A) Write-ups of meetings and interviews with Region 5, Region 6, OAQPS, and OECA personnel found in Section F and Section H workpapers.

**CONCLUSION:** Individuals from Region 5, Region 6, OAQPS, and/or OECA have stated that HQ issued directives that limited regions' efforts to address ethylene oxide emissions as shown in Tables 1 through 7 in the Details section of this WP.

**DETAILS:**

Evaluator reviewed Section F and Section H workpapers to summarize interviewee responses on whether HQ issued the following directives:

- Not to issue a press release or release the May 2018 monitoring results for the Sterigenics facility in Willowbrook, Illinois in June 2018.
- Pull down the Region 5 Sterigenics website after it went live for about an hour on 8/22/18.
- Not to send 114 letters to facilities.
- Not to conduct monitoring.
- Not to conduct inspections at ethylene oxide-emitting facilities unless invited by state to conduct joint inspection.
- Seek permission from OAQPS before starting any modeling.
- Not to work with ATSDR.

Below are the results of this review.

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	3/24/20
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/17/20

Table 1 below shows three individuals from Region 5 stating that HQ ordered Region 5 not to issue a press release or release the May 2018 monitoring results for the Sterigenics facility in Willowbrook, Illinois in June 2008.

Row	Region / Office	Name of individual / Title	Statement regarding directive	Whether individual provided any emails related to the directive
1	(b) (6)  [Redacted]  (Link: H.02.d > section “Participants”)	(b)(6) [Redacted] ( <a href="#">Link:</a> H.02.d > section “Participants”)	(b) (5) [Redacted]	Yes, but none of the emails show HQ’s directive. (b) (6) [Redacted]  - [Redacted]  - [Redacted]  - [Redacted]  - [Redacted]

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	3/24/20
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/17/20



				<p>(b) (6)</p> <p>[REDACTED]</p>
2	<p>(b) (6)</p> <p>[REDACTED]</p>	<p>(b)(6)</p> <p>[REDACTED]</p> <p>(<a href="#">Link:</a> H.02.c &gt; section "Participants")</p> <p>(<a href="#">Link:</a></p>	<p>(b) (5)</p> <p>[REDACTED]</p>	<p>No.</p>

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	3/24/20
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/17/20

	H.02.c > section "Participants"		(b) (5)	
3	(b) (6)  (Link: H.02.g > section "Participants")	(b)(6) (Link: H.02.g > section "Participants")	(b) (5)	No.

Pull down the Region 5 Sterigenics website after it went live for about an hour on 8/22/18

Table 2 below shows three individuals from Region 5 stating that HQ directed Region 5 to take down its Sterigenics website after it went live for about an hour on 8/22/18.

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	3/24/20
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/17/20





			(b) (5)	
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<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	3/24/20
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/17/20



2	<p>(b) (6)</p> <p>(Link: H.02.d &gt; section "Participants")</p>	<p>(b)(6)</p> <p>(Link: H.02.d &gt; section "Participants")</p>	<p>(b) (5)</p>	<p>Yes. (b) (5), (b) (6)</p> <p>.02.d &gt; <a href="#">Link</a>: Source Y)</p>
3	<p>(b) (6)</p> <p>(Link: H.02.e &gt; section "Participants")</p>	<p>(b)(6)</p> <p>(Link: H.02.e &gt; section "Participants")</p>	<p>(b) (5)</p>	<p>No.</p>

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	3/24/20
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/17/20

			(b) (5)	
4	<p>(b) (6)</p> <p>(Link: H.02.f &gt; section "Participants")</p>	<p>(b)(6)</p> <p>(Link: H.02.f &gt; section "Participants")</p>	<p>(b) (5)</p> <p>(b) (5)</p>	No.

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	3/24/20
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/17/20



			(b) (5)	
5	(b) (6)  (Link: H.02.h > section "Participants")	(b)(6) (Link: H.02.h > section "Participants")	(b) (5)	Yes. (b) (5), (b) (6)
			(b) (5)	

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	3/24/20
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/17/20

			(b) (5)	
			(b) (5)	
6	(b) (6) (Link: H.03.a > section "Participants")	(b)(6) (Link: H.03.a > section "Participants")	(b) (5)	No.

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	3/24/20
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/17/20

			(b) (5)	
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<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	3/24/20
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/17/20

			(b) (5)	
7	(b) (6)  (Link: H.04.a > section "Participants")	(b)(6)  (Link: H.04.a > section "Participants")	(b) (5)	No.
8	(b) (6)  (Link: H.03.b > section "Participants")	(b)(6)  (Link: H.03.b > section "Participants")	(b) (5)	No.
9	(b) (6)	(b)(6)  (Link: H.02.x > section "Participants")	(b) (5)	No.

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	3/24/20
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/17/20

	(b) (6) (Link: H.02.x > section "Participants")		(b) (5)	
10	(b) (6) (Link: H.02.s > section "Participants")	(b)(6) (Link: H.02.s > section "Participants")	(b) (5)	No.

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	3/24/20
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/17/20

			(b) (5)	
11	(b) (6)  (Link: H.02.r > section "Participants")	(b)(6)  (Link: H.02.r > section "Participants")	(b) (5)	No.
12	(b) (6)  (Link: H.02.p > section "Participants")	(b)(6)  (Link: H.02.p > section "Participants")	(b) (5)	No.
13	(b)(6)	(b)(6)	(b) (5)	No.

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	3/24/20
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/17/20

	( <a href="#">Link: H.02.o</a> > section "Participants")	(b)(6)  ( <a href="#">Link: H.02.o</a> > section "Participants")	(b) (5)	
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**B** [Link:](#) [Link:](#) [Link:](#) [Link:](#) [Link:](#) Not to Conduct Monitoring

Nine individuals in Region 5, Region 6, and OAQPS (including (b) (6) ) have stated that there was such a directive (b) (5) as shown in Table 4.

**Table 4: Individuals from Region 5, Region 6, and OAQPS that have stated that HQ did not allow them to conduct monitoring**

Row	Region / Office	Name of individual / Title	Statement regarding directive	Whether individual provided any emails related to the directive
1	(b) (6)	(b)(6)  ( <a href="#">Link:</a> H.02.b > section "Participants")	(b) (5)	No.

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	3/24/20
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/17/20

	H.02.b > section "Participants")			
2	(b) (6) [REDACTED] (Link: H.02.x > section "Participants")	(b)(6) [REDACTED] (Link: H.02.x > section "Participants")	(b) (5) [REDACTED]	No.
3	(b) (6) [REDACTED] (Link: H.02.y > section "Participants")	(b)(6) [REDACTED] (Link: H.02.y > section "Participants")	(b) (5) [REDACTED]	No.
4	(b) (6) [REDACTED] (Link: [REDACTED])	(b)(6) [REDACTED] (Link: H.02.s > section "Participants")	(b) (5) [REDACTED]	No.

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	3/24/20
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/17/20



	H.02.s > section "Participants")			
5	(b) (6) [REDACTED]  (Link: H.04.b > section "Participants")	(b)(6) [REDACTED]  (Link: H.04.b > section "Participants")	(b) (5) [REDACTED]	No.
6	(b) (6) [REDACTED]  (Link: H.02.r > section "Participants")	(b)(6) [REDACTED]  (Link: H.02.r > section "Participants")	(b) (5) [REDACTED]	No.
7	(b) (6) [REDACTED]  (Link: H.02.p > section "Participants")	(b)(6) [REDACTED]  (Link: H.02.p > section "Participants")	(b) (5) [REDACTED]  [REDACTED]	No.

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	3/24/20
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/17/20

			(b) (5)	
8	(b)(6) (Link: H.02.o > section "Participants")	(b)(6) (Link: H.02.o > section "Participants")	(b) (5)	No.
9	(b) (6) (Link: H.02.aa > section "Participants")	(b)(6) (Link: H.02.aa > section "Participants")	(b)(6)	No.

**C** [Link: WP M.07.b.3 - Indexed Congressional Request Draft Report - Chapter 3.docx](#) Not to Conduct Inspections Unless Invited by State to Conduct Joint Inspection

Seven individuals in Region 5, Region 6, OAQPS, and OECA have stated that there was such a directive or that HQ did not allow them to conduct inspections at ethylene oxide-emitting facilities unless invited by the state as shown in Table 5 with one of them providing emails that supported what (b) (6) had heard.

**Table 5: Individuals from Region 5, Region 6, OAQPS, and OECA that have stated that HQ did not allow them to conduct at ethylene oxide-emitting facilities unless invited by state to conduct joint inspection**

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	3/24/20
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/17/20

Row	Region / Office	Name of individual / Title	Statement regarding directive	Whether individual provided any emails related to the directive
1	(b) (6)  ( <a href="#">Link</a> : H.02.e > section "Participants")	(b)(6)  ( <a href="#">Link</a> : H.02.e > section "Participants")	(b) (5)	No.
2	(b) (6)  ( <a href="#">Link</a> : H.02.d > section "Participants")	(b)(6)  ( <a href="#">Link</a> : H.02.d > section "Participants")	(b) (5)	Yes. (b) (5), (b) (6)  (H.02.d > <a href="#">Link</a> : Source U)

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	3/24/20
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/17/20



			(b) (5)	
5	(b) (6) [REDACTED] (Link: H.04.b > section "Participants")	(b)(6) [REDACTED] (Link: H.04.b > section "Participants")	(b) (5) [REDACTED]	No.
6	(b) (6) [REDACTED] (Link: H.02.q > section "Participants")	(b)(6) [REDACTED] (Link: H.02.q > section "Participants")	(b) (5) [REDACTED]	No.

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	3/24/20
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/17/20

	H.02.q > section "Participants")			
7	(b) (6) [REDACTED] (Link: H.02.m > section "Participants")	(b)(6) [REDACTED] (Link: H.02.m > section "Participants")	(b) (5) [REDACTED]	No.

**D** [Link:](#) Seek Permission from OAQPS to Conduct Modeling

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	3/24/20
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/17/20

Four individuals in Region 5 and OAQPS (including (b) (6) ) have stated that there was such a directive (b) (5) as shown in Table 6 with one of them providing an email that memorialized what (b) (6) had heard.

**Table 6: Individuals from Region 5 and OAQPS that have stated that HQ wanted regions to get permission from OAQPS or to coordinate with OAQPS before conducting modeling**

Row	Region / Office	Name of individual / Title	Statement regarding directive	Whether individual provided any emails related to the directive
1	(b) (6)  H.02.d > section "Participants") (Link:	(b)(6)  (Link: H.02.d > section "Participants")	(b) (5)	Yes. (b) (5), (b) (6)  . (H.02.d > Link: Source V)
2	(b) (6)	(b)(6)  (Link: H.02.b > section "Participants")	(b) (5)	No.

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	3/24/20
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/17/20







	(b) (6) [REDACTED] (Link: H.02.b > section "Participants")	H.02.b > section "Participants")	(b) (5) [REDACTED]	
3	(b) (6) [REDACTED] (Link: H.02.e > section "Participants")	(b)(6) [REDACTED] (Link: H.02.e > section "Participants")	(b) (5) [REDACTED]	No.
4	(b) (6) [REDACTED] (Link: H.02.h > section "Participants")	(b)(6) [REDACTED] (Link: H.02.h > section "Participants")	(b) (5) [REDACTED]	No.
5	(b) (6) [REDACTED] (Link: H.02.p	(b)(6) [REDACTED] (Link:	(b) (5) [REDACTED]	No.

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	3/24/20
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/17/20

	> section "Participants")	H.02.p > section "Participants")	(b) (5)	
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Reviewer Comment (and Date of Review)	Team Response (and Date of Response)	Resolution (and Date of Resolution)
(b) (5)  No additional comments. RML 4/17/20	(b) (5)  BC, 4/1/20	WP approved. RML 4/17/20

<b>Prepared by:</b>	<b>Date</b>
Bao Chuong	3/24/20
<b>Approved by:</b>	<b>Date</b>
Renee McGhee-Lenart	4/17/20